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The Impact of Accreditation on the Quality of Hospital Care: KwaZulu-Natal Province, Republic of South Africa

October 2003





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The Quality Assurance Project (QAP) is funded by the U.S. Agency for International Development (USAID) under Contract Number GPH-C-00-02-00004-00. The project serves developing countries eligible for USAID assistance, USAID Missions and Bureaus, and other agencies and nongovernmental organizations that cooperate with USAID. QAP offers technical assistance in the management of quality assurance and workforce development in healthcare, helping develop feasible, affordable approaches to comprehensive change in health service delivery. The project team includes prime contractor University Research Co., LLC (URC), Initiatives Inc., and Joint Commission Resources, Inc. The work described in this report was carried out by the Quality Assurance Project under USAID Contract Number HRN-C-00-96-90013, managed by the Center for Human Services, URC's nonprofit affiliate, in partnership with Joint Commission Resources, Inc. and Johns Hopkins University.

The Impact of Accreditation on the Quality of Hospital Care: KwaZulu-Natal Province, Republic of South Africa

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Foreword by James R. Heiby

Commentaries by Stuart Whittaker,
Marie Muller, and Marilyn Keegan,
and by Anne L. Rooney



Abstract

The number of countries implementing accreditation programs in their healthcare systems has grown in the past decade, but accreditation's impact has not been tested rigorously using a randomized control trial. The purpose of this study was to conduct such a trial in a developing country setting and to air its implications. The KwaZulu-Natal (KZN) province of South Africa was chosen because it had just contracted with the Council for Health Services Accreditation of Southern Africa (COHSASA) to introduce hospital accreditation into KZN public hospitals. Following discussions between COHSASA and the Joint Commission International (JCI), a joint research team representing the Medical Research Council (MRC) of South Africa and JCI, under the sponsorship of the USAID Quality Assurance Project, was engaged to study the impact of the COHSASA accreditation program on KZN hospitals.

The KZN province agreed that 20 randomly selected public hospitals, stratified by size, could be part of the study. Ten of these hospitals entered the accreditation program in 1998; the other ten, which served as a control, entered about two years later. The study prospectively measured the effects of the COHSASA hospital accreditation program on various indicators of hospital care. The study used survey data from the COHSASA accreditation program measuring

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Abstract *Continued*

hospital structures and processes, along with eight indicators of hospital quality of care collected by an independent research team. The indicators of hospital quality had been developed by consensus of an advisory committee in South Africa. The indicators were: nurse perceptions of quality, client satisfaction, client medication education, accessibility and completeness of medical records, quality of peri-operative notes, hospital sanitation, and labeling of ward stocks. Indicators of mortality and morbidity were dropped because of difficulty in achieving comparability across the hospitals. The investigators compared the performance of the ten hospitals participating in the accreditation program (intervention hospitals) with the ten not yet participating (control hospitals).

About two years after accreditation began, the study found that intervention hospitals significantly improved their average compliance with COHSASA accreditation standards from 38 percent to 76 percent, while no appreciable increase was observed in the control hospitals (from 37 percent to 38 percent). This improvement of the intervention hospitals relative to the controls was statistically significant and seems likely to have been due to the accreditation program. However, with the exception of nurse perceptions of clinical quality, the independent research team observed little or no effect of the intervention on the eight quality indicators. Limitations of the study design may have influenced these results. Several intervention hospitals were still trying to achieve accredited status at the time of the second COHSASA survey, and in general the full impact of the program may take longer than the interval measured in this study.

The practical implications of the results of this study are: (1) the COHSASA-facilitated accreditation program was successful in increasing public hospitals' compliance with COHSASA standards, and (2) additional work is needed to determine if improvements in COHSASA structure and process standards result in improved outcomes.

Acknowledgements

The research team wishes to express its gratitude to the following individuals and organizations for serving on the Research Project Steering Committee and for their support and important contributions to this research study: Professor Stuart Whittaker, COHSASA, Chair; Professor Ronald Green-Thompson, KZN Department of Health; Dr. Ivan McCusker, COHSASA Board of Directors and Technology Advisory Committee; Dr. Ken Yamashita, USAID/South Africa; Dr. Nico Walters, Medical Research Council (MRC); and Ms. Anne Rooney, Quality Assurance Project/Joint Commission International.

We thank the following for the foreword and commentaries:

James R. Heiby, Chief Technical Officer for Quality Assurance and Workforce Development, USAID Bureau for Global Health, Office of Health, Infectious Diseases and Nutrition.

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Recommended citation

Salmon JW, Heavens J, Lombard C, and Tavrow P with foreword by Heiby, JR, and commentaries by Whittaker S, Muller M, Keegan M, and Rooney AL. 2003. The Impact of Accreditation on the Quality of Hospital Care: KwaZulu-Natal Province, Republic of South Africa. *Operations Research Results* 2(17). Bethesda, MD: Published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project, University Research Co., LLC.

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Foreword

James R. Heiby¹

Hospitals in developing countries are complex organizations. We would like to be able to measure how well they provide healthcare and help them to do better. In developed countries, one of the central strategies for this is accreditation. Typically, a disinterested, external group develops and publishes standards that describe how experts think hospital care should be organized and what resources are needed to provide acceptable care. Whenever possible, evidence-based standards are used directly or the functional accreditation standards have evidence-based standards embedded within them. Trained observers visit the hospitals and measure the extent to which they meet the standards. A hospital that scores high enough is “accredited” for a specified period of time. Few developing countries have established hospital accreditation programs, but interest is growing. The expectation is that these programs will provide an incentive to improve care and help the hospital staff see what specific changes are needed. Of course, these programs cost money, and developing countries need to make careful choices in allocating their limited resources.

The logic of accreditation is compelling: A standard might require, for example, that every patient’s medical record include the results of the physical examination. The Council for Health Services Accreditation for Southern Africa (COHSASA) program, which is the subject of the study reported here, includes 6,000 such standards covering all the functions of a general hospital. These standards help hospitals in the program to improve structures and processes that they think will result in better health outcomes. The main question addressed by the study is, If a hospital successfully goes through the accreditation process, can we measure improvement in health outcomes? The experience of developed countries has shown such efforts to be frustrating and inconclusive. In light of the need by developing countries to make careful choices and the few if any published reports available, studies are urgently needed.

Thus the introduction of a new accreditation program in KwaZulu-Natal Province opened up a unique opportunity to undertake a randomized controlled trial of the impact of accreditation in a developing country. The study report and the two companion commentaries show that even a randomized control design did not overcome all of the practical difficulties of evaluating the health impact of accreditation in a developing country setting. Some of these difficulties were related to the variable and sometimes inconsistent way hospitals actually work. But the central issue proved to be the

barriers to measuring the health outcomes that were central to the study.

This study is unique in that it used a random assignment of hospitals to intervention and control groups in order to evaluate the impact of an accreditation program on hospital performance. We know of no other randomized experimental design that studied the impact of accreditation programs. This rare opportunity was brought about by the cooperation of: KwaZulu-Natal Province of the Republic of South Africa, COHSASA, the Medical Research Council of South Africa, the Quality Assurance Project (including both the Joint Commission International and University Research Co.), and the United States Agency for International Development.

The study began in November 1998 when KwaZulu-Natal Province (KZN) signed a contract with COHSASA to undertake the COHSASA-facilitated accreditation program in 29 KZN hospitals, with 10 hospitals randomly assigned to the intervention group and 10 to the control group, stratified by size. (One of the intervention hospitals dropped out of the accreditation midway through the study, and so to retain comparability of the intervention and control groups, a similar-sized hospital was removed from the control group, leaving nine hospitals in the intervention group and nine in the control for this part of the study.) The accreditation program involved the baseline measurement of many structural and process variables in each participating hospital and then feedback of the measurements to each hospital. Technical assistance followed to help the hospitals improve quality and subsequent accreditation measurements. The last steps were a repeat of periodic measurements of performance in accordance with the standards, feedback of results, and technical assistance to help reach previously unreached standards. The accreditation standards are grouped according to crucial topics; hospitals were graded on each topic and eventually either denied or awarded partial or full accreditation if they achieved minimum levels of compliance for each topic.

During the two-year study, COHSASA measured the accreditation variables twice and performed the rest of the program as normal in the nine intervention hospitals. They measured the accreditation variables as unobtrusively as possible in the nine control hospitals, but did not perform any of the other components of the accreditation program, meaning no feedback of results and no technical assistance, until after the research was completed. Meanwhile, a separate research team measured the research indicators in both the intervention and control hospitals.

The primary research report by Salmon, Heavens, Lombard, and Tavrow carefully delineates between the research indi-

¹ James R. Heiby is Chief Technical Officer for Quality Assurance and Workforce Development, USAID Bureau for Global Health, Office of Health, Infectious Diseases and Nutrition.

cators on the one hand and the COHSASA accreditation measurements on the other. Because of the randomized nature of the research design and the regularity of the COHSASA data collection, there is little doubt that the significant improvements in the COHSASA accreditation measurements were due to the accreditation program. After about two years, the intervention hospitals' performance to standards according to the accreditation measurements increased from 38 percent to 76 percent, while no appreciable increase occurred in the control hospitals (37 percent to 38 percent). This finding is important because it is, as far as we know, the first time that it has been shown conclusively that a facilitated accreditation program significantly improved hospital performance in relation to accreditation standards.

The research indicators are a different story, according to Salmon, et al. First, with one exception the study found little or no effect of the accreditation program on the research indicators. The one exception is "nurse perceptions of clinical quality," which showed a positive program effect. Second, several methodological difficulties occurred that could explain this lack of clear findings. Third, the research indicators are few in number, only eight at the end of the study (there had been 12 at the start of the study but four were eliminated mid-study because of the difficulty in achieving reliable measurements). These eight are, for the most part, not patient health outcomes but downstream process indicators: nurse perceptions of clinical quality, patient satisfaction, medical education of patients, medical record access and accuracy, medical record completeness, peri-operative notes completeness, ward stock labeling, and hospital sanitation. As a result, the authors conclude that the lack of association between the program and improvement in the research indicators could be due to either: (1) the inability of the program to influence these indicators, or (2) methodological problems in the study itself, such as lack of sufficient time and progress toward accreditation during the limited period of measurements.

The commentary by Whittaker, Muller, and Keegan addresses these potential methodological problems and why they are the likely causes for the lack of findings between the program and the research indicators. These commentators note that early delays in research funding combined with the fixed contracted schedule for implementation of the accreditation program caused serious problems in research data collection. Thus, the baseline measurement of the research indicators should have occurred at about the same time as the baseline accreditation measurement in each study hospital (both intervention and control), and the next measurement of the research indicators in each study hospital should have occurred at about the same time in each hospital relative to the time that the second accreditation measurements were collected and, for intervention hospitals, fed back to the hos-

pital. Further, adequate time should have passed between the feedback of the baseline accreditation measurements and the subsequent measurement that enabled the hospital to react to the feedback and engage in the accreditation improvement program. However, this timeline was not followed in many cases and thus the comparison of the baseline and follow-up measurements of accreditation variables and research indicators are not comparable. Furthermore, after reviewing research field reports and interviewing research team data collectors, Whittaker et al. conclude that insufficient planning and communication among centrally based research staff, field data collectors, and hospital staff led to serious failures that further biased the validity of the data. They also identify a cluster of accreditation measurements most closely associated with each research indicator. The relative scores of the research indicators and accreditation clusters differ from one indicator to another, sometimes agreeing and sometimes not. The commentators feel this difference is a cause for concern, one that may have compromised the validity of the research indicators. They recommend that future research spend additional effort testing research indicators and the procedures for measuring them ahead of time. Finally, these commentators point out the difficulty that resource-constrained hospitals have in achieving standards and the need for facilitated approaches under such conditions.

The commentary by Rooney places the current study in context. She summarizes the difficulties in linking the structure and process of healthcare to the outcomes of healthcare, including problems in finding comparable metrics of structure, process, and outcome; the varied and probabilistic nature of the amount of time for change to occur; and the difficulty in finding an appropriate comparison group, particularly in countries such as the U.S., where accreditation is widespread and long-standing. The South African study addresses all of these challenges according to Rooney: It provides for a randomized control; it sheds light on the vexing problems of the time it takes for effects to be measurable; and it addresses the difficult problems of relating structure, process, and outcomes. In addition, she reviews several studies that support or counter the thesis that accreditation programs relate to outcomes in hospitals and the important role of the South Africa study in the discussion.

Although this study does not provide conclusive evidence of the impact of an accreditation program on a selected set of research indicators, it does highlight impressive gains of improved performance according to accreditation standards. The report and its commentaries also address a range of methodological issues and lessons that can inform future research, so needed in this vital area, relevant to developing countries throughout the world.

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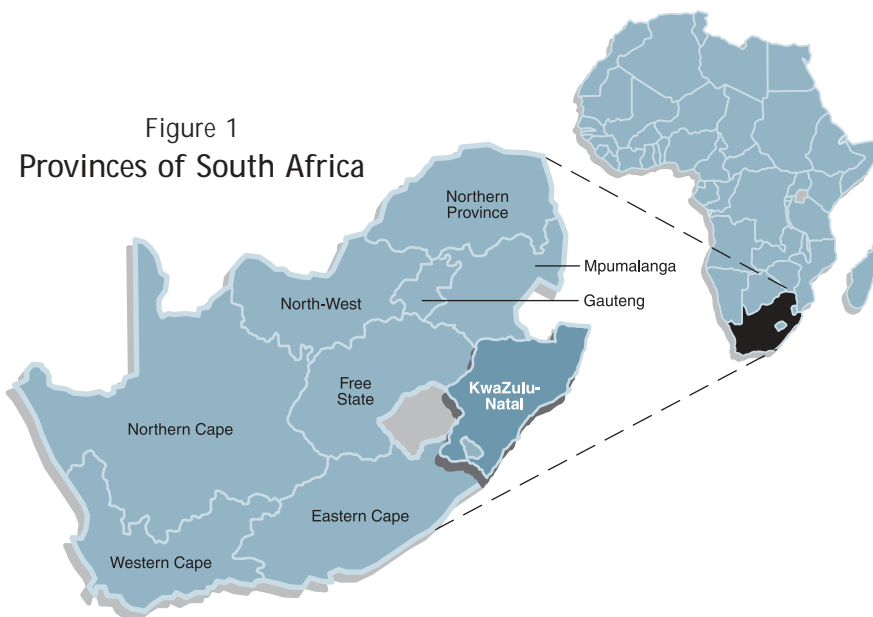
J. Warren Salmon, John Heavens, Carl Lombard, and Paula Tavrow

I. Introduction

Concerns over cost and quality have created a climate where decision makers at all levels are seeking objective data for evaluating healthcare organizations. In a number of countries, mechanisms of external evaluation, such as accreditation, have been introduced as a systematic response to this need. Accreditation is generally viewed as a formal process by which an authorized body, either governmental or nongovernmental, assesses and determines whether a healthcare organization meets applicable, predetermined, and published standards. Accreditation standards are intended to be optimal and achievable, and they are designed to encourage continuous quality improvement efforts within accredited organizations. Accreditation is usually a voluntary process where organizations choose to participate, rather than are required to do so by law or regulation (Rooney and vanOstenberg 1999).

While the number of countries implementing hospital accreditation is mounting because the process is generally believed to be beneficial, to date there is little conclusive evidence that the accreditation process actually improves the quality of care offered in hospitals (Walsh 1995; Viswanathan and Salmon 2000; Shaw 2001). Since

Figure 1
Provinces of South Africa



accreditation usually entails a significant cost, determining whether it is worthwhile is crucial, especially in regions where resources are constrained, such as among public hospitals in South Africa. A challenge is to develop valid and meaningful indicators of key hospital structures, processes, and outcomes expected to be affected by an accreditation program, so that specific changes arising from accreditation could be tracked across multiple sites and over time.

II. Background

South Africa is a mid-range developing country with a per capita income of US\$ 6900 in 1999. Its population

in 2000 was estimated to be 43 million, of whom 75 percent were African, 13 percent white, 9 percent "colored," and 3 percent Indian (www.infoplease.com). Large disparities exist between the poor rural communities and the seemingly "first world" cities. Starting in 1994, the first post-apartheid government in South Africa sought a needed transformation of the health sector. After many years of the apartheid government's neglect, the system was inequitable, fragmented, and severely underfinanced in the provision of vital health services. South Africa spends approximately 8 percent of its GDP on healthcare, but the amount spent on poor, rural residents is still disproportionately low.

Abbreviations

ALPHA	Agenda for Leadership in Programs for Healthcare of the International Society for Quality in Health Care
AORR	Anaesthetic Operation and Recovery Record
COHSASA	Council for Health Services Accreditation of Southern Africa
CQI	Continuous quality improvement
C/S	Cesarean section
FAP	Facilitated Accreditation Programme
GDP	Gross Domestic Product
HTAC	Health Care Technology Advisory Committee
ICU	Intensive care unit
ID	Identification
ISQua	International Society for Quality in Health Care
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JCI	Joint Commission International
JCWC	Joint Commission Worldwide Consulting
KZN	KwaZulu-Natal
LOS	Length of stay
MRC	Medical Research Council
NA	Data not available
NC	Non-compliant
PC	Partially compliant
QAP	Quality Assurance Project
QI	Quality Improvement
RA	Research assistant
SD	Statistical deviation
TB	Tuberculosis
USAID	U.S. Agency for International Development

To motivate and assist hospitals to achieve better quality of care, the Council for Health Services Accreditation of Southern Africa (COHSASA) was established in 1995 in Cape Town. COHSASA is a private, not-for-profit accreditation organization. Initially, its clients were mainly private hospitals in South Africa that contracted with COHSASA to participate in its accreditation program so that they could strive to achieve higher standards. In 1998, COHSASA signed an agreement with the KwaZulu-Natal (KZN) Province for the first province-wide public hospital accreditation activity in the country.

COHSASA's accreditation approach is based on facility empowerment and continuous quality improvement (CQI) processes. COHSASA facilitators initially assist each participating facility to understand the accreditation standards and to perform a self-assessment (baseline survey) against the standards. The data gathered during the survey are recorded on forms and then entered into COHSASA's computer database for analysis and reporting purposes. Detailed written reports on the level of compliance with the standards and reasons for non-conformance are generated and sent to the hospital for use in its quality improvement program. Next, the facilitators assist the hospital in implementing a CQI program to enable the facilities to improve on standards identified as sub-optimal in the baseline survey. This preparatory phase usually takes hospitals from 18 months to two years to complete.

Lastly, the hospital enters the accreditation (external) survey

phase, when a team of COHSASA surveyors who were not involved in the preparatory phase conduct an audit. The accreditation team usually consists of a medical doctor, a nurse, and an administrator who spend an average of three days evaluating the degree to which the hospital complies with the standards and recording areas of non-compliance. Hospitals found by COHSASA's accreditation committees to comply substantially with the standards are awarded either pre-accreditation or full accreditation status. The former status encourages the respective institution to continue with the CQI process, which should help it stay on the path to eventual full accreditation status (Whittaker et al. 2000; Whittaker 2001).²

III. Objective of the Study

The purpose of this study was to assess prospectively, using a randomized control trial, the effects of an accreditation program on public hospitals' processes and outcomes in a developing country setting. The study was designed to examine the impact of an accreditation program on: (a) the standards identified for measurement and improvement by the accrediting organization (in this case, COHSASA), and (b) quality indicators developed by an independent research team.

KZN was selected as the research site for several reasons. First, COHSASA and KZN were just completing negotiations to launch the accreditation program there, so

² For more information about COHSASA's accreditation approach, see <www.cohsasa.co.za>.

it was possible to randomly assign hospitals to intervention and “waiting list” control categories. At the time of the study, KZN had 114 hospitals, of which 63 were public hospitals under the control of the province; of these, 53 were acute care hospitals, and 10 were psychiatric and long-term facilities. The sample was drawn from the 53 acute care hospitals. Second, the KZN provincial health department was receptive to having a research study of this kind conducted in KZN. Third, collaborative relations existed between two accrediting bodies, JCI and COHSASA, which facilitated the involvement of JCI and one of its collaborators—the Quality Assurance Project (QAP)—in managing the research and participating in the selection of the quality indicators to be measured.

IV. Research Methodology

The study design was a prospective, randomized control trial with hospitals as the units of analysis. The study used survey data from the COHSASA accreditation program and quality indicator data collected by an independent research team composed of South African and American investigators. The researchers compared the performance of a stratified sample of KZN public hospitals participating in the accreditation program (intervention hospitals) with a sample of those not yet participating (control hospitals) over a 24-month interval.

A. Sampling

The sampling frame consisted of 53 public sector hospitals under the management of the KZN province.

Table 1
Hospital Stratification and
Number of Hospitals Randomly Selected

Size of Hospital (Number of Beds)	Number	Number of Hospitals Sampled	Sampling Fraction	Control Sample	Intervention Sample
50–150	11	4	36%	2	2
151–400	26	10	38%	5	5
401–1000	11	4	36%	2	2
1001+	5	2	40%	1	1
TOTAL	53	20	38%	10	10

To ensure a balanced design with respect to service and care characteristics, researchers stratified the hospitals by size (number of beds) into four categories. Within each stratum a simple random sample without replacement was drawn (see Table 1; a detailed profile of the selected hospitals is in Appendix Table A.)

The sample size calculation was based on the observed accreditation scores of seven public sector hospitals (six hospitals from the North West province and one KZN academic hospital that was excluded from this study) that COHSASA had previously accredited. Two outcomes from these hospitals were used: (1) the overall compliance score before and after accreditation, and (2) the medical inpatient service compliance score before and after accreditation. For these seven hospitals, the mean overall compliance scores were 61 percent (before) and 87 percent (after), and the mean medical inpatient service score was 65 percent (before) and 91 percent (after). That is, both outcome scores improved about 26 percent.

For a significance level of 5 percent, power of 80 percent, and an expected effect size of 25 percent, approximately three hospitals per arm (intervention and control) would be necessary or six hospitals in total. Since this would not capture hospitals from all strata, the sample size was increased to 10 hospitals per arm (20 hospitals in total).

B. Data Collected

Two types of data were used for this study: before and after measures of compliance with COHSASA standards, and indicators of hospital quality collected at two points in time. The former were collected by COHSASA surveyors or teams hired by COHSASA; the latter were collected by research assistants hired by the research team.

1. COHSASA Standards

As part of its accreditation process, COHSASA surveyors and each participating hospital's internal team assessed approximately 6,000 criteria (measurable elements) in 28 service elements. The service elements included management, operating theater, health and safety,

inpatient care, housekeeping, amenities, outpatient care, laboratory, pharmaceutical, critical care, and social work (a complete list is in Appendix Table B). The accreditation standards required that systems and processes be established in clinical and non-clinical activities of all services. For example, hospitals were required to develop training programs to assist staff to keep abreast of developments, establish infection control, set up resuscitation and safety systems, introduce risk monitoring, and implement procurement programs to ensure that facilities and equipment were safe and functioning properly.

Each criterion was scored as “non-compliant,” “partially compliant,” or “fully compliant.” It also was classified as “mild,” “moderate,” “serious,” or “very serious.” For example, if an item were labeled “non-compliant, very serious,” that would indicate that the standard was not being met and the label represented a very serious breach. Certain criteria were given more weight in calculation of overall scores and determination of accreditation status. For each service element, the percentage of criteria scored as fully compliant was calculated, and an overall compliance score for the hospital was determined. To achieve accreditation status, a hospital had to be compliant on a subset of criteria judged to be critical (more than 400) and to have obtained a compliance score of 80 percent or higher in each service element.

The study used COHSASA standards data from two points in time: baseline surveys (self-assessments) and accreditation (external) surveys. In intervention hospitals, the hospital staff conducted their self-assessment as they normally would in launching an accreditation process,

but these data were validated carefully by COHSASA surveyors and, in consultation with hospital staff, modified as needed to serve as the baseline data. The external survey was conducted by external surveyors, contracted by COHSASA, who had not been part of the baseline validation study. In control hospitals, to ensure that the staff were not influenced by the accreditation process, they were not given a set of accreditation standards to prepare for a self-assessment (as is usual in the accreditation program). Instead, COHSASA surveyors conducted the baseline survey on their own. COHSASA surveyors, not external surveyors, also conducted the final surveys in the control hospitals.

COHSASA survey teams were multidisciplinary, comprised of a medical practitioner and two nurses. They interviewed hospital staff, consulted hospital records, and observed procedures and operations to determine the degree to which the service elements met the requirements of the standards and criteria. All survey data were recorded on the standard data capture forms that had been developed and tested by COHSASA over the previous seven years. Members of the surveying teams met regularly to compare their findings. Where unexplained differences were identified, these areas were reassessed. The external survey teams met with the intervention hospital staff at the end of the external survey of the intervention hospitals to report their findings. The accuracy of the data collection and the reporting process were assessed by the intervention hospital staff who received a written draft report of the survey findings and were given an opportunity to comment.

2. Indicators of Hospital Quality

To develop indicators for hospital quality, a workshop was held in South Africa in May 1999. Present at the workshop were South African healthcare professional leaders, the managing director of COHSASA, a representative from JCI, and the principal investigators for the research study. (Appendix Table C provides the initial set of indicators and is followed by a list of the workshop participants.)

Workshop participants brainstormed and discussed possible indicators, following these steps:

- Agreed upon topic areas for consideration (e.g., surgical procedures),
- Listed possible indicators in each of these topic areas,
- Discussed and agreed on which would be feasible and which would not,
- Categorized them as indicators of process or outcome,
- Ranked the feasible indicators in order of priority, and
- Agreed on and documented the data sources for these indicators.

Twenty-two indicators were initially identified and categorized by type (outcome, process, or structure), feasibility (high, medium, or low), and change expected (high, medium, or low). This was followed by a protracted process of “round-robins” among the research team members and the QAP staff in a process of agreeing which indicators were likely to be feasible, valid, and reliable; developing questionnaires and data collection tools; and documenting the agreed-upon indicators and their data collection

processes fully. The research team took these steps to further refine the indicators and data collection methodology:

- Brainstormed other possible indicators, such as an indicator of financial management;
- Reviewed feasibility, reliability, and validity issues with a statistician;
- Developed questionnaires and data collection forms, and documented indicators fully and established sample volumes;
- Compiled an indicator manual for research assistants;
- Trained research assistants, pilot tested initial indicator set, analyzed data to establish feasibility, reliability, and validity, and revised them accordingly;
- Revised the data collection forms and indicator manual, and re-trained research assistants;
- Collected initial data sets from all participating hospitals (intervention and control);
- Analyzed data again to establish feasibility, reliability, and validity, and revised indicators accordingly; and
- Revised the data collection forms and indicator manual, and re-trained research assistants.

This process resulted in 12 indicators for the first round of data collection (see Table 2). However, based on preliminary analysis of data collected from the first round, the research team recommended to the steering committee that some indicators be dropped. The steering committee—composed of representatives from the research team, the sponsors of the research, COHSASA, and several South

African medical experts—decided to drop the two indicators relating to surgical wound infections and time to surgery because only nine hospitals (six intervention and three control) performed surgery regularly and many of the records lacked information on infections and times. Despite its limitations, the committee did retain the indicator on completeness of peri-operative notes and extended this to include any form of significant incision or anesthesia.

The committee also dropped the indicator of neonatal mortality rate, because the research assistants had great difficulty in finding reliable data due to the high variation in approaches to documenting neonatal deaths among the various hospitals. Transferring newborns soon after birth was common, but sometimes hospitals reported transfers even when they recorded deaths. Finally, the indicator of financial solvency was discarded because the KZN provincial government had implemented strict budgeting controls across all hospitals in the region with reportedly no additional funds being assigned. Hence, it was unlikely that the COHSASA process would affect this indicator. These decisions resulted in eight quality indicators (see Table 2).

C. Data Management Procedures

1. COHSASA Data

Data collected by the accreditation surveys were entered by COHSASA data typists onto screen images of the data collection forms and verified by a reviewing team. Thereafter it was transferred to the research team for further processing. Once entered, the data were

stored on Microsoft Access database software.

2. Quality Indicator Data

Data collected by the research assistants were recorded on the various data capture forms in the field and then checked for completeness after the day's visit to the hospital. The number of questionnaires completed was noted. The questionnaires were delivered to the Medical Research Council (MRC) data typists and the data rechecked during the data entry. The data were stored as ASCII files and the number of data collection forms on the files was checked against the research assistants' reported numbers and the number required according to the study design. All discrepancies were queried. The encoded questionnaires are stored at the MRC. To protect privacy, no names of patients or staff were entered into the database.

D. Data Analysis

Data were analyzed using SPSS version 9. Chi-squares, correlations, and ANOVAs were performed on both sets of data.

E. Timeframe for Data Collection

The data collection for the study was determined in part by the contractual arrangements between COHSASA and the KZN Department of Health. The baseline COHSASA surveys for intervention hospitals were conducted from December 1998–February 1999 and for control hospitals in May–June 1999. External surveys for both intervention and control hospitals were conducted from May–October 2000. As shown in Table 3, the average

Table 2
Indicators of Quality of Hospital Care Used in the Study

Indicator	Method	Rationale	Whether Retained for 2 nd Round
Nurse perceptions of clinical quality, participation, teamwork	26-item questionnaire for up to 50 nurses per hospital 4-part Likert scale (agree a lot, some; disagree some, a lot)	Related to overall hospital management, cooperation and empowerment of nursing staff, nurse satisfaction	Yes
Patient satisfaction	18-item questionnaire for up to 50 patients (in- and outpatients) 4-part Likert scale (agree a lot, some; disagree some, a lot)	Overall "flag" indicator of quality and related to patients' rights	Yes
Medication education	13-item questionnaire for up to 50 patients (in- and outpatients) 4-part Likert scale (agree a lot, some; disagree some, a lot)	Indicated safe and efficacious medication treatment in post-hospital discharges	Yes
Medical record accessibility and accuracy	Request 100 medical records; calculate retrieval rate and accuracy	Important for information management and continuity of care	Yes
Medical record completeness	15-item record audit of 50 records (from the 100 obtained)	Important for information management and continuity of care	Yes
Completeness of peri-operative notes	21-item notes audit of 50 files of peri-operative notes	Indicated quality of overall surgical and anesthesia care	Yes
Completeness and accuracy of ward stock medicine labeling	4-item review of pharmacy stock labeling (correct contents, strength, batch number, expiration date) in wards	Important for safe and effective medication management on wards	Yes
Hospital sanitation	Observation of availability and condition of soap, water, toilets, baths/showers, hand drying	Important to overall hospital infection prevention and control	Yes
Neonatal mortality rate	Review of hospital mortality reports for 12-month period	Outcome measure for overall quality of care	No
Surgical wound infection rates	Record audit of nosocomial infections in 50 surgical files (collected above)	Outcome measure related to effectiveness of hospital's infection control program	No
Elective surgery: time from admission to surgery	Calculation of time between admission and administration of anesthesia for 50 patients (using same files as above)	Indicated timeliness and efficiency; process measure that could "proxy" for patient outcome	No
Financial solvency	Financial review of budget outlays and shortfalls in past calendar year	Related to overall hospital management and good budgeting practices	No

interval between baseline and external COHSASA surveys was about 16 months, but the interval was significantly longer for intervention hospitals (19 months) than control hospitals (14 months) ($F=48.9$, $p<.000$).

Because of the time it took to develop and test the quality indicators, the first round of indicator data collection did not occur until September–December 1999 for both intervention and control hospitals. On average, this was 7.4 months

after COHSASA collected the baseline survey data. Because the first round of indicator data was collected at the same time for both types of hospitals and the baseline COHSASA surveys had been collected at different times, there

was a significant difference in the interval between the baseline survey and the first indicator survey ($F=87.6$, $p<.000$).

The research design required that the second round of indicator data be conducted shortly after the COHSASA accreditation survey to reduce possible confounding. In general, this timetable was followed; however, for some hospitals the second indicator survey occurred up to two months before the accreditation survey. Both types of surveys were conducted from May–October 2000. For both the intervention hospitals and control hospitals, about nine months elapsed between the rounds of indicator data collection (see Table 3). The main reason for the relatively short interval

between the indicator surveys was that the control hospitals wished to launch the accreditation process as soon as possible. The data from the second COHSASA survey would serve as the baseline for these hospitals' efforts to achieve accreditation. Because the research design required that each round of indicator data be collected during the same time period and that indicator data be collected shortly after the external surveys occurred, the interval between indicator surveys was determined by the accreditation roll-out. A detailed plan for collection of the second round of indicator data was approved by the research steering committee. The implications of the relatively short interval between rounds of indicator data collection are discussed below.

V. Results

A. Compliance with COHSASA Standards

During the study period, intervention hospitals made substantial progress in complying with COHSASA standards. As shown in Figure 2, intervention hospitals improved their average overall scores from 48 percent to 78 percent, whereas control hospitals maintained the same score throughout (43 percent). (The very large intervention hospital postponed the second survey, so this analysis was based on only nine intervention hospitals.) Appendix Table B shows baseline and external scores for all 28 service elements. Significant positive change was observed in 20 of 21 elements having sufficient intervention hospitals to make a statistical test. No meaningful change occurred in any service element in the control hospitals. While the intervention hospitals had on average 17 months³ to improve their scores as compared to 14 months for control hospitals, the significant differences across most service elements strongly suggest that the accreditation program, not the time interval, accounted for most of the observed change. Moreover, no correlation was found between final accreditation scores of the intervention hospitals and the time between COHSASA surveys.

As an added test, the research team did a sub-analysis of those standards that COHSASA has deemed

Table 3
Intervals between COHSASA and Indicator Surveys (in Months)

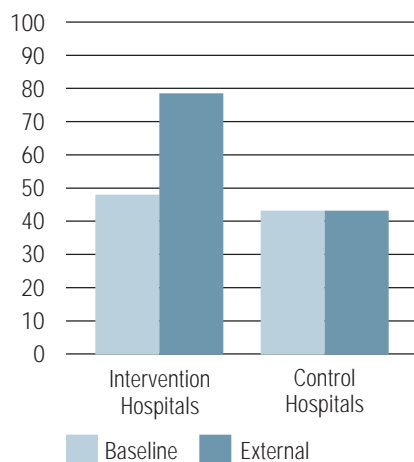
		Interval between COHSASA Surveys (1 & 2)	Interval between Indicator Surveys (1 & 2)	Interval between 1st COHSASA and 1st Indicator Surveys	Interval between 2nd COHSASA and 2nd Indicator Surveys
Inter- vention hospitals	Mean	18.8*	8.3	10.1*	-.4
	Minimum	15.6	6.2	8.2	-1.5
	Maximum	21.0	11.4	11.9	.4
Control hospitals	Mean	13.7*	9.4	4.7*	.4
	Minimum	11.5	6.0	3.0	-2.1
	Maximum	16.3	12.0	6.6	1.6
Total	Mean	16.3	8.9	7.4	.0
	Minimum	11.5	6.0	3.0	-2.1
	Maximum	21.0	12.0	11.9	1.6

Notes: For 18 hospitals (9 intervention and 9 control): Both very large hospitals were excluded from this table, because the very large intervention hospital did not complete its accreditation survey during the time period of the study (December 1998–December 2000) and the very large control hospital was an outlier. Negative values in the last column indicate that the indicator survey was performed before the accreditation survey.

* Significant difference between intervention and control hospitals ($p<.000$).

³ The intervention hospitals generally did not start working to improve standards until they had seen the baseline survey reports, which was about two months after the baseline surveys were conducted.

Figure 2
Average Overall Score on
COHSASA Standards,
by Intervention Status,
over Time



“critical” for a specific function. Within the 28 service elements evaluated in the accreditation process, some are not applicable to all hospitals: 19 service elements were generic across all of the study hospitals. These elements yielded 424 critical criteria, drawn mainly from the following service elements: obstetric and maternity inpatient services, operating theater and anesthetic services, resuscitation services, pediatric services, and medical inpatient services. At baseline the intervention and control hospitals showed similar levels of compliance to the critical standards. The intervention hospitals had an overall compliance of 38 percent (range 21 percent to 46 percent) compared to the control hospitals with 37 percent compliance (range 28 percent to 47 percent). After the intervention period, the intervention hospitals reached a level of 76

percent compliance on the critical standards (range 55 percent to 96 percent) whereas the controls were unchanged with 38 percent compliance (range 25 percent to 49 percent). The difference in means was significant ($p < 0.001$).

Despite this dramatic improvement in COHSASA scores, only one intervention hospital achieved full accreditation by the study closure date, with two others reaching pre-accreditation (intermediate) status. These results suggest that for public hospitals in South Africa participating in an accreditation program for the first time, the process is rigorous and demanding.

B. Impact on Indicators of Quality

Because each quality indicator measured a different process or outcome, and used highly varying data collection methodologies, the researchers felt they could not combine them into a single measure of quality. Instead, each indicator was analyzed separately. For control and intervention hospitals, the researchers determined the mean scores at Time 1 and Time 2 and calculated the mean change. Then a “mean intervention effect”—the difference between the change observed in the intervention hospitals and that observed in the control hospitals—was calculated and p-values were determined (see Table 4).

Analysis was performed at the level of randomization (hospital), not at the individual or record level within hospitals. In this section, we present and discuss the results for each of

the eight indicators. (The complete list of indicator results, with standard deviations and confidence intervals, is in Appendix Table D.)

Nurse perceptions of quality. It is widely acknowledged that nurses’ performance has a strong bearing on the quality of care offered to patients. Many of the COHSASA standards relate to nursing functions and call for goal-directed leadership of nurses, a coordinated and participative approach to nursing, efficiency in allocation of nursing resources, and so on.

The 26-item questionnaire administered to nurses sought to measure nurses’ perceptions of the hospital work environment, both for themselves and their patients.⁴ The survey assessed nurses’ views on their relationships with other professionals and departments, possibilities for teamwork, and the general quality of patient care. In both rounds of data collection, more than 20 nurses were interviewed at all hospitals except one small control hospital. Altogether, 922 nurses were interviewed in the first round and 942 in the second.

Nurses’ overall perceptions of care at the intervention hospitals increased slightly (59 percent to 61 percent), whereas they declined at the control hospitals (61 percent to 57 percent). The mean intervention effect was 6 percentage points, which was statistically significant ($p < 0.030$). The effect was more pronounced in the mid-sized hospitals. However, there was no correlation between nurses’ overall perceptions of care and either improvement in scores or the final COHSASA scores.

⁴ The questionnaire was based in part on an instrument previously developed by Marie Muller, Professor of Nursing and Dean of the Faculty of Education Nursing at Rand Afrikaans University, Johannesburg, South Africa.

Table 4
Summary of Average Quality Indicator Scores for Intervention and Control Hospitals over Time, with Intervention Effect

Indicator	Intervention (N=10)			Control (N=10)			Intervention Effect	P-Value
	Time 1	Time 2	Change	Time 1	Time 2	Change		
1. Nurse perceptions	59.3	60.8	1.5	60.8	56.5	-4.2	5.7	.031
2. Patient satisfaction	86.9	91.5	4.6	87.0	90.1	3.1	1.5	.484
3. Medical education	42.9	43.1	0.2	41.5	40.0	-1.5	1.7	.395
4. Medical records: accessibility	85.4	77.5	-7.9	79.4	68.4	-11.0	3.1	.492
5. Medical records: completeness	47.1	49.1	2.0	48.6	44.9	-3.7	5.7	.114
6. Completeness of peri-operative notes	70.2	72.7	2.5	65.2	69.6	4.4	-1.9	.489
7. Ward stock labeling	66.0	81.8	15.8	45.6	49.6	4.0	11.8	.112
8. Hospital sanitation	59.7	62.8	3.1	50.2	55.7	5.5	-2.4	.641

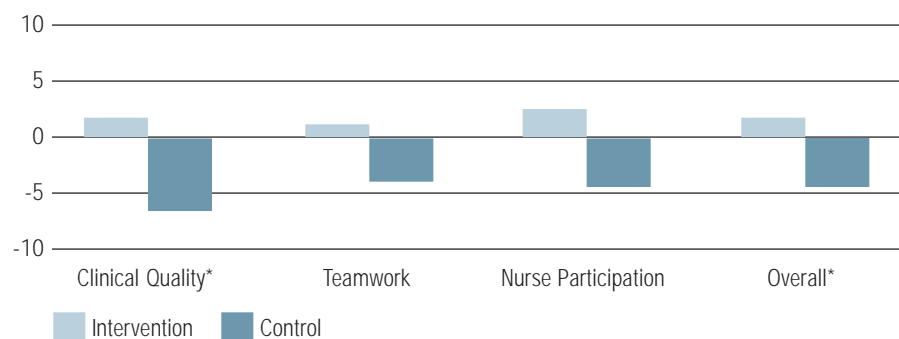
Note: All scores were standardized to a 100-point scale, with 100 as high. Positive intervention effects represent improvements in intervention hospitals that exceed the control hospitals' improvements. P-values are based on ANOVA model with experimental group and hospital size as main effects.

A factor analysis identified three subscales that showed adequate reliability. They corresponded to nurses' perception of: (1) clinical quality, (2) teamwork and cooperation, and (3) participation in decisions. In all of these, nurses' perceptions at intervention hospitals seemed to increase, while they decreased in control hospitals (see Figure 3). The mean intervention effect was significant only for clinical quality. As expected, the researchers found a positive correlation between nurses' perceptions of quality and the final external COHSASA score. However, there was a significant inverse correlation between nurses' perception of their participation in decision making and final COHSASA scores. This may mean that hospitals where doctors and managers "take charge" of the preparations for accreditation have better success rates.

It appears that the accreditation program may have arrested a general decline in nurses' morale and their perceptions of their hospitals' care. However, budget restrictions and limited supplies and equipment may have dampened the

effect of accreditation on nurses' views. Meanwhile, the rising AIDS burden in South Africa, the failure of hospital salaries to improve appreciably, and the constant emigration of nurses from South African may be having a general depressive effect.

Figure 3
Changes in Nurses' Perceptions of Clinical Quality, Teamwork, and Nurse Participation in Intervention and Control Hospitals

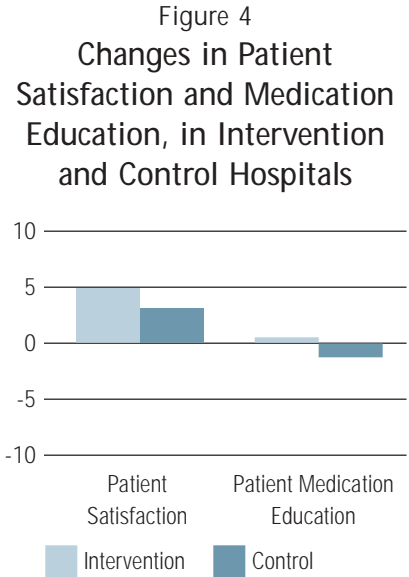


* Significant at $p < .05$. Positive changes indicate improvements; negative changes indicate declines. Changes are expressed in percentage points.

Patient satisfaction. Although patient satisfaction in developing countries has not been studied as extensively as in industrialized countries, it clearly is an important indicator of how patients are experiencing care. Certain COHSASA standards explicitly call for greater recognition of patients' rights and greater patient participation in the care received. The 18-item questionnaire was developed after a review of the literature on patient satisfaction and input from technical advisors. Altogether, 954 patients were interviewed in the first round and 969 in the second, both with roughly equal numbers of in- and outpatients.

The research team found that patients' satisfaction with care improved somewhat both in intervention hospitals (from 87 percent to 92 percent) and in control hospitals (from 87 percent to 90 percent), yielding a mean intervention effect of only about 2 percentage points ($p=.484$). Bigger hospitals tended to have less satisfaction, probably because larger and more complex hospitals tend to care for the more ill patients, putting greater stress on the hospital's whole system, which may be reflected in overall patient satisfaction (Figure 4).

Because such a high level of satisfaction was unexpected, the research team recalibrated the instrument to reduce the halo effect. In this approach, any positive item on which a patient did not agree "a lot" (or any negative item on which the patient did not disagree "a lot") was classified as dissatisfied. This led to about a 10 percent reduction in satisfaction, but did not alter the general trend or heighten significantly the difference between intervention hospitals (from 79



Note: Changes are expressed in percentage points. No change is significantly different. Positive changes indicate improvements; negative changes indicate declines.

percent to 86 percent) and control hospitals (79 percent to 84 percent). While several studies in South Africa found lower levels of satisfaction (Davies 2000; Goldstein and Price 1995), our generally favorable results may indicate that poor, rural South Africans appreciate the care they receive and/or are reticent to express dissatisfaction to unknown researchers. The efforts of the KZN Department of Health to upgrade physical facilities across the province during the study period may have influenced patients' expressed satisfaction. Satisfaction did not correlate with patient age or language. However, for both intervention and control hospitals, inpatients were significantly more satisfied than outpatients, and less educated patients were significantly more satisfied than more educated ones.

Patient medication education. Ensuring appropriate pharmacotherapy for patients, as well as their correct adherence to medication regimens, remains a major challenge for hospitals. The rising cost of medications, the extended disease burden among the population, and the shortage of professional pharmacists for clinical care contribute to inadequate pharmaceutical advice and treatment. Pharmaceutical services comprise one of COHSASA's 28 service elements, and pharmaceutical issues are also imbedded in other service elements. Hence, medication education was considered both an important indicator of quality as well as an item that the research team anticipated would be responsive to the accreditation program. For this indicator, 915 patients were interviewed in the first round and 892 in the second.

The research team found that patients' overall medication education score stayed almost the same in intervention hospitals (from 42.9 percent in Time 1 to 43.1 percent in Time 2) and declined marginally in control hospitals (from 41.5 percent to 40.0 percent), yielding an insignificant mean intervention effect of only 1.7 percentage points (Figure 4). In both rounds of data collection, extremely high proportions of patients at both types of hospitals reported that the pharmaceutical staff was courteous and respectful (94 percent in Time 1 to 98 percent in Time 2), felt that the pharmacist ensured that they knew how to take the drug (91 percent to 91 percent), believed that they received the actual drug prescribed (90 percent to 96 percent), and felt sure that they knew how to take the drug (88 percent to 96 percent). Unfortunately, we cannot know whether the

patients' perceptions of correct pharmacology were based in fact. While patients seemed pleased with the pharmacy, very few reported that they could have a private conversation with their pharmacist (5 percent to 2 percent) or could ask a question of their pharmacist (28 percent to 28 percent).

Patients were much less satisfied with the medical staff, and their dissatisfaction appeared to be growing. In both intervention and control hospitals, there were significant declines in how many patients reported that doctors explained their medications fully (63 to 57 percent), nurses explained medicines also (50 to 39 percent), and doctors and nurses took enough time with them (49 to 46 percent).

Medical record retrieval and accuracy. The patient's chart remains the best means of tracking medical diagnoses made and medications prescribed, communicating patient information to other caregivers, and ensuring appropriate continuity and effectiveness of care. For clinical staff to use medical records for quality care, it is essential that they be readily accessible and accurate. Hence, an important indicator of care is the degree to which records can be retrieved rapidly, are legible, and are correctly filled out. For this indicator, the research assistants were directed to seek to retrieve about 100 records per hospital. In Time 1, they sought to retrieve 1738 records (mean per hospital: 87); in Time 2, they sought to retrieve 3648 records (mean per hospital: 182).

The research team found that the accessibility of medical records declined over time for both interven-

tion and control hospitals, but the decline was slightly larger in control hospitals.⁵ In intervention hospitals, the percentage of records retrieved fell from 85 to 78 percent; in control hospitals, it dropped from 79 to 68 percent. The mean intervention effect of 3 percentage points was not significant.

Overall, the percentage of records retrieved declined from 82 to 72 percent. It is not known if some records were more likely to be "lost" than others—e.g., in cases where the patient died. Variability among hospitals was high: retrieval rates ranged from 48–53 percent to 97 percent. The percentage of correct records retrieved (i.e., the patient's name and in- /outpatient status were correct) showed nearly the same size and trend: it declined from 80 to 71 percent. The fact that fewer than three in four records were correctly retrieved could have implications for proper patient management.

Medical record completeness. For good continuity of inpatient care, patients' charts should contain full information about admission (patient identification number, date, time, history, examination findings, diagnosis, treatment plan, medicines ordered, doctor attending) and discharge (patient identification number, discharge date, discharge diagnosis, discharge plan, medicines, doctor attending). Without these 15 elements, medical personnel may have difficulty determining how the patient's care has been managed, and effective clinical auditing for quality improvement is hindered.

For this study, 950 inpatient records were examined at Time 1 (mean per hospital: 48) and 940 records were

examined in Time 2 (mean per hospital: 47). Research assistants were asked to calculate the number of elements present, not whether the elements seemed accurate. The two aspects of this indicator—admission (9 elements) and discharge (6 elements)—were scored separately. While the research assistants were asked to determine if each element was present fully, somewhat, minimally, or not at all, the investigators decided to reduce this scoring to a two-point scale (full versus partial/none) to reduce potential subjectivity associated with scoring of "somewhat" versus "minimally." Scores therefore indicate the percentage of medical records in which admission and discharge elements were fully present.

The research team found that admission scores rose somewhat for intervention hospitals (52 to 56 percent) and dropped slightly for control hospitals (53 to 51 percent). The estimated indicator effect for admission completeness was 6 percentage points, which is not statistically significant ($p=0.136$). For discharge scores, intervention hospitals showed almost no change (40 percent in both time periods), while control hospitals declined somewhat (43 to 37 percent). The estimated indicator effect for discharge completeness was equivalent to the admission data (6 percentage points, $p=0.173$).

Overall, the average medical record lacked four of nine admission elements and four of six discharge elements, with no real difference between the two hospital groups at either time period. No individual hospital performed particularly well: The maximum admission score was

⁵ One intervention hospital refused to retrieve any records in Time 1. It was removed as an outlier for this indicator.

69 percent and discharge score was 52 percent in Time 2. Clearly, the level of completeness is quite low, even for hospitals in the accreditation program.

Completeness of peri-operative notes.

Documentation of a patient's clinical status throughout his or her operation (including preparation and follow-up) is an important clinical communication and risk management tool. As mentioned earlier, the steering committee recommended that the team maintain the inclusion of peri-operative notes as an indicator by including *all* surgery using anesthesia performed in the operating theater. The research assistants obtained this additional information for the baseline period of the first data collection when they returned to the hospitals. Cesarean births were also included. It should be noted that several hospitals do not employ surgeons; some hospitals perform only emergency operations, transferring out all other cases; and some do not have recovery rooms. Due to the nature of the procedures performed, a number of items relating to pre-operative and anesthetic aspects were scored "not applicable" for a large proportion of the notes evaluated. These items were therefore not used in scoring this indicator. Only 14 of the original 21 items were used and the percentage completeness was calculated for each note.

Results showed that for the intervention hospitals the completeness of peri-operative notes rose slightly from 70 to 73 percent, whereas for control hospitals it rose from 65 to 70 percent, yielding an insignificant

negative intervention effect. Dividing the notes into subscales—of pre-operative, anesthetic, or operation notes—did not yield any significant positive intervention effect.

Labeling of ward stock medications.

Improper labeling and maintenance of stocks of medicines held on the wards for inpatients can lead to serious medication errors and adverse consequences for patients. Labeling is the domain of pharmacy staff, who are expected to record correctly the name, drug contents, strength, batch number, and expiration date for all containers of drugs they send to the wards. The ward nurses are expected to ensure that the drugs they administer are properly labeled and that expired drugs are discarded. Problems arise when containers are sent back to the pharmacy for refilling; batch numbers and expiration dates are often not changed. Compliance with COHSASA standards can be expected to minimize these errors. For this study, research assistants were asked to record whether containers of ward stock drugs were properly labeled and not expired. They assessed 970 containers in Time 1 (average per hospital: 49) and 998 containers in Time 2 (average per hospital: 50).

Ward stock labeling improved in both intervention hospitals (from 66 to 82 percent) and in control hospitals (from 46 to 50 percent) over time, with a mean indicator effect of nearly 12 percentage points, which was not significant ($p < 0.112$). Control hospitals were significantly weaker than intervention hospitals at both time periods. The main weaknesses in labeling related

to batch numbers and expiration dates.⁶ Among intervention hospitals, labels with batch numbers rose from 68 to 82 percent, and those with expiration dates rose from 84 to 90 percent. Both of these stayed fairly constant in control hospitals: Labels with batch numbers rose from 46 to 50 percent and those with expiration dates fell from 66 to 64 percent. For both types of hospitals, all other labeling in Time 2 exceeded 90 percent.

The percentage of expired drugs on wards was nearly the same in Time 1 for intervention hospitals (6 percent) and control hospitals (5 percent). This rose to 12 percent for intervention hospitals in Time 2 due to one outlier hospital that had an extremely high expiration rate of 58 percent. For control hospitals in Time 2, expired drugs were nearly the same (4 percent) as their Time 1 score.

Hospital sanitation. Cleanliness of a hospital and the availability of supplies to enable proper sanitation (e.g., soap, water, toilet paper) are important contributors to infection prevention and control efforts. These supplies can also contribute to patient and provider satisfaction. Moreover, good hospital sanitation is an indicator of management effectiveness and proper allocation of resources. A number of COHSASA service elements have sanitation components. For this indicator, the research assistants assessed the sanitation in up to 25 wards per hospital. They examined six items: availability of soap, water, paper towels, and toilet paper and whether toilets were clean and in working order.⁷ They assessed 351 wards in Time 1 (average per hospital: 18)

⁶ This indicator assessed only the presence or absence of batch numbers and expiration dates. It did not determine their accuracy.

⁷ They also assessed whether the showers were clean and the taps worked, but because so many wards lacked these features, they were removed from the analysis.

and 339 wards in Time 2 (average per hospital: 17).

The research team developed a composite score for the six sanitation items (standardized on a scale of 1–100, with 100 high). The trend in both types of hospitals was a slight improvement in sanitation over time: Intervention hospitals increased from 60 to 63 and control hospitals from 50 to 56. Because the control hospitals increased more, the intervention effect was negative but not significant. Table 5 shows the individual components of the composite score. Water availability and toilet cleanliness rose the most in both types of hospitals. However, intervention hospitals experienced a decline in the percentage of toilets functioning. In both Times 1 and 2, intervention hospitals seemed to have slightly better sanitation than control hospitals, but the difference was not significant. The changes in water availability can probably be attributed to the provincial effort to upgrade facilities through the mobilization of sanitary engineers. Running water was available in 98 percent of the study hospitals at the time of the second round of data collection. On the other hand, less than half of the hospitals had soap or paper towels.

VI. Discussion

This study is noteworthy because it represents one of the first randomized control trials conducted to assess the impact of an accreditation process (Shaw 2001). The willingness of the KZN Department of Health to accommodate such a study within its contractual agreement with COHSASA made this trial possible, as did COHSASA's cooperation. While the investigators

Table 5
Percentage of Hospital Wards Having Basic Sanitation Items,
in Intervention and Control Hospitals over Time

	Intervention Hospitals (N=10)		Control Hospitals (N=10)	
	Time 1	Time 2	Time 1	Time 2
Soap available	42	44	36	35
Water available	91	99	82	97
Toweling available	23	34	17	21
Toilet clean	57	63	48	61
Toilet paper available	60	60	45	47
Toilet functioning	85	77	73	74

did not interview hospital administrators and KZN provincial health managers, the province seems to be engaged in a number of related activities that show considerable promise. The government is making new investments in the public health sector to overcome the legacy of the past regime. Organizational transformation led by the KZN Department of Health appears to be aiding the hospitals to best use their resources; the commitment to COHSASA hospital accreditation is one such quality improvement strategy.

A. COHSASA Standards

The study demonstrated that the accreditation program had a substantial impact on compliance with standards delineated by the program. In every service element, a highly significant impact of the COHSASA program was observed. Yet only one hospital achieved full accreditation status during the course of the study. (A second intervention hospital achieved full accreditation status after completion of the study.) It is possible that many

of the KZN public hospitals, especially those in rural areas, may need more time to fully implement the accreditation program. Some hindering factors probably were the heightened burden of disease (due to AIDS, TB, cholera), staff departures, critical budgetary and resource constraints, and the need to upgrade management and clinical staff skills.

B. Quality Indicators

While the study clearly showed that the accreditation program affected compliance with standards, the quality indicators selected by a diverse group of South African and American experts seemed to have been impacted only marginally, with the exception of nurse perceptions of quality. There are two possible explanations: (1) the study methodology, in hindsight, may have had flaws; or (2) the accreditation program may not be affecting quality of care as measured by our indicators.

Let us start by considering whether the study methodology had flaws.

The study's main potential weaknesses relate to the sampling procedures, the timeframe for data collection, and the indicators chosen. Regarding sampling, thanks to the cooperation of the KZN province, the researchers were able to randomly assign hospitals to control or intervention status, thereby permitting the study to adhere to scientific principles. However, it is possible that the stratification method chosen (bed size) was not the most meaningful. It may have been better to stratify the hospitals by factors known to affect their ability to comply with standards, such as staffing levels, staff qualifications, or budget levels.

The timeframe for the indicator data collection is another source of concern. Due to factors beyond the researchers' control, the first quality indicator survey occurred on average ten months after the COHSASA baseline survey in intervention hospitals (see Table 3). It is possible that these hospitals had already made considerable progress that was not captured because the first round was too late to be a true baseline. However, an examination of the indicators at Time 1 revealed that intervention and control hospitals were roughly comparable except for two indicators (ward stock labeling and hospital sanitation). This suggests that major changes in the indicators had not already occurred (see Table 4).

A more serious issue is whether sufficient time elapsed between Time 1 and Time 2 to properly gauge the impact of the accreditation activity on the indicators. As mentioned earlier, only nine months on average elapsed between the

two data collection rounds, with one hospital being re-measured after only six months. Given what is known about organizational change, this time interval may have been too short to capture the eventual outcomes of the accreditation program. However, the second round was at nearly the same time as the external accreditation survey; for some hospitals this could be the moment when compliance with standards would be highest. Also, no correlation was found between indicator scores and the interval between indicator surveys, which ranged from six to 12 months. This suggests that additional time between indicator surveys may not have made a significant difference in results.

The last methodological issue concerns the quality indicators chosen. It is possible that the indicators did not fully capture the impact of the COHSASA accreditation process on quality of care. In a developing country setting where clinical information is not computerized and record keeping is generally sub-optimal, it is difficult to arrive at valid clinical indicators that are also easily retrievable in a limited time. The final set lacked some critical outcome indicators—such as mortality and nosocomial infections—which have intrinsic interest and value. Consequently, this study cannot comment on whether the COHSASA program improved health outcomes as measured by reduced mortality or morbidity. Moreover, the investigators had limited time and resources to fully test the feasibility, validity, and reliability of a large number of indicators.

However, one could argue that the final set of indicators does assess a

number of diverse and important quality of care issues—such as sanitation, drug labeling, medication education, patient satisfaction, medical records, and nurse perceptions. These indicators and their measurement procedures appeared to be reliable and to have face validity, and thus could be used in future studies to assess hospital quality in developing countries.⁸

If we presume that the methodology, while not ideal, was sufficient to answer the study questions, then we need to understand why we did not find that the COHSASA accreditation program had the expected impact on our indicators of quality. A recent study from the U.S. could show no relationship between accreditation scores and the outcomes for which data were available to the investigator to study relationships between scores and outcomes (Griffith et al. 2002). There are several possible reasons why we did not find the COHSASA program to have the expected impact, some or all of which may be relevant. First, the COHSASA program may not have achieved sufficient compliance with standards to lead to changes in the quality indicators. There may be a threshold phenomenon in which full compliance with many COHSASA standards is required before positive impact occurs in a quality indicator, and if so, that threshold may not have been reached by the second round of data collection. However, we examined data from the hospital that had achieved accreditation status and did not find significant improvements in the indicators.

Second, it is possible that the influence of the COHSASA program on quality of care was affected by other forces operating on public

⁸ The instruments used to collect the indicator data may be obtained from the Quality Assurance Project.

hospitals in KZN. Specifically, budget limitations, reduced staffing levels, insufficient staff training, delayed infrastructural improvements, insufficient capacity building, a heightened patient load, and sicker patients all could counteract or overwhelm the effect of increased standards compliance. Alternatively, the KZN Department of Health's noteworthy efforts during the study period to improve all public hospitals' infrastructure, financial management, and equipment maintenance may have moderated the impact of the accreditation program on the quality indicators.

Third, the COHSASA accreditation program may be highly effective in changing structures, administrative procedures, and organizational processes, but not as effective in improving the indicators of care that we measured. Doctors' behaviors are notoriously difficult to change. In a review of hospital accreditation, Duckett (1983) noted that the areas that showed the least change were those associated with the medical staff. One could argue that hospitals entering an accreditation program are likely to concentrate first on structural and procedural standards and that attention to clinical processes and outcomes would follow later. Because we did not examine the standards individually, we do not know if those that improved related more to the former. It is more likely that those standards that hospital staff found "easier" to implement because they did not require doctors' involvement or ongoing attention—such as writing job descriptions, posting procedures, and so on—were the ones that changed first.

Some might maintain that adherence to standards must occur for a certain

period before measurable changes in patient care are detected. Hence, it would be unlikely to observe changes in quality indicators immediately after an accreditation exercise is completed. While this argument has intuitive appeal, we found no evidence in the literature of a time lag between standards compliance and quality of care. The dilemma for researchers is that the longer the interval after an intervention, the more difficult and controversial it is to attribute change to the intervention.

Lastly, the COHSASA program may not be emphasizing the standards most likely to result in a demonstrable impact on quality of care as measured by the eight quality indicators. Although we did not study how COHSASA facilitators spend their time, it is possible that we would have observed more change in the indicators if the facilitators had put more emphasis on clinical standards and meeting patients' needs. COHSASA's recent decision to incorporate clinical outcomes measurement and technology assessments into its program may invigorate the effort to address patient outcomes. Unfortunately, there are still many areas of clinical care lacking evidence-based standards.

VII. Conclusion

This study provides clear evidence that hospitals participating in the COHSASA program in the KZN province significantly improved their compliance with COHSASA accreditation standards following the introduction of the program. No increase in standards compliance was observed in the control hospitals, indicating that the observed

improvements in the intervention hospitals can be credited to the accreditation program. Similarly dramatic results were obtained for two different definitions of the standards, one using the complete set of COHSASA standards across the 28 service areas and a second using 424 critical criteria from 19 service areas selected by the research team.

However, the study did not find a similar pattern among independently developed quality indicators. The question is whether this lack of observed impact was due to limitations of the research design or to some characteristics of the accreditation program itself. Although we do not know with certainty the answer to this question, several limitations of the study design could have prevented us from observing a large impact of the accreditation program on the quality indicators. These limitations include the relatively short time allowed to achieve measurable results following the introduction of the program, factors other than the accreditation program that might have influenced performance differentially in the intervention and control hospitals, and the lack of in-depth probing into causal mechanisms. It is possible that the program's full impact will be felt later. A follow-on study measuring the same indicators at a later point in time would be valuable, because how much time is required is still an empirical issue.

An alternative explanation is that the COHSASA accreditation program, as constituted when the study was conducted, was successful in improving structures and procedures but did not have the desired impact on quality of care in resource-constrained public hospitals.

The program may not have been able to sufficiently counteract the effects of other forces on these hospitals, even while a provincial health department was actively engaged in improving the hospital sector. It is highly possible that

COHSASA's new emphasis on clinical outcomes measurement and heightened attention to evidence-based standards will cause the program to have more impact on clinical care in the future. The slight upward trend noted in many of the

indicators is most likely arising from a fruitful collaboration between the province and accrediting body, one that could evolve and lead to better patient care in the years to come.

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Appendix

Table A
Profile of Study Hospitals (1999)

Size of Hospital	Type of Hospital	Hospital Setting	No. of Beds	No. of Annual Admissions	No. of Nurse Posts Filled	% of Nurse Posts Vacant	Admissions per Nurse	No. of Operations per Mo. (Ave.)	No. of Pharmacy Scripts per Month (Ave.)	No. of Specialty Services Offered
Small	Control	Urban	54	2666	32	22.0	83	10	800	0
	Interv.	Urban	102	15589	226	6.2	69	350	3461	4
	Control	Urban	120	12309	189	19.2	65	250	13407	4
	Interv.	Rural	150	5485	124	22.5	44	200	1600	2
Medium	Control	Rural	170	3856	108	11.5	36	18	1385	3
	Control	Rural	181	4379	122	29.5	36	70	3453	3
	Control	Rural	204	10823	143	7.1	76	238	1512	1
	Control	Rural	261	9066	136	18.6	67	75	1935	1
	Control	Rural	266	4731	221	35.0	21	250	6088	3
	Interv.	Urban	276	13715	198	4.3	69	102	4334	0
	Interv.	Rural	296	11744	405	3.8	29	213	1726	4
	Interv.	Peri-urban	300	14107	205	10.5	69	153	9215	1
	Interv.	Peri-urban	307	6720	190	4.5	35	322	5570	3
	Interv.	Urban	338	16000	174	3.9	92	363	5616	0
Large	Interv.	Urban	460	17552	242	24.8	73	320	9214	3
	Interv.	Urban	485	28689	753	8.9	38	700	13000	7
	Control	Rural	598	NA	426	22.4	NA	200	13914	6
	Control*	Peri-urban	1620	24673	1072	21.3	23	400	11553	8
Very large	Control	Peri-urban	1200	36976	1142	25.5	32	879	22200	6
	Interv.	Peri-urban	1645	38640	1358	12.2	28	997	17398	9

* Number of beds and other statistics reported for this hospital represent the combined total of the standard hospital as well as a permanent psychiatric component. The standard hospital used for the study has less than 1000 beds.

NA = data not available.

Table B
COHSASA Standards Compliance Scores of Intervention and Control Hospitals over Time

Service Element	Intervention Hospitals				Control Hospitals				95% Confidence Limits			
	No. of Hospitals	Mean Baseline	Mean External	Mean Change	No. of Hospitals	Mean Baseline	Mean External	Mean Change	Mean Intervention Effect	Lower	Upper	P- Value
Management service	9	50	79	29	10	42	44	2	27	17	37	<.001
Administrative support	9	57	73	16	10	56	52	-4	20	4	36	.038
Nursing management	9	55	87	32	10	51	50	-1	33	24	43	<.001
Health and safety	9	35	75	40	10	28	32	4	36	23	51	<.001
Infection control	9	45	88	43	10	39	42	3	40	27	52	<.001
Operating theater	9	57	86	29	10	50	53	3	26	16	35	<.001
Sterilizing and disinfectant	9	47	81	34	10	33	35	2	32	22	41	<.001
Medical inpatient	8	49	78	29	10	44	46	2	27	17	35	<.001
Pharmaceutical	9	41	75	34	10	42	38	-4	38	25	52	<.001
Pediatric inpatient	8	51	78	27	10	44	46	2	25	17	33	<.001
Maternity inpatient	9	53	82	29	10	52	51	-1	30	23	36	<.001
Surgical inpatient	9	48	81	33	10	46	46	0	33	25	42	<.001
Laundry	9	30	68	38	10	23	24	1	37	26	47	<.001
Housekeeping	9	37	73	36	10	33	32	-1	37	24	51	<.001
Maintenance	9	51	74	23	10	43	44	1	22	11	34	.004
Resuscitation	9	31	83	52	10	25	25	0	52	43	61	<.001
Food	9	41	73	32	10	38	38	0	32	24	41	<.001
Diagnostic	9	44	79	35	10	38	39	1	34	22	46	<.001
Critical care category 2	2	46	92	46	4	58	61	3	43	15	70	NA
Casual	7	48	81	33	5	40	43	3	30	17	44	NA
Outpatient	8	46	83	37	9	40	43	3	34	20	47	NA
Occupational	3	42	85	43	4	43	47	4	39	16	62	NA
Physiotherapy	7	46	84	38	4	38	42	4	34	24	45	NA
Laboratory	9	46	85	39	8	43	40	-3	42	31	53	<.001
Medical life support	9	37	74	37	10	21	23	2	35	22	49	.001
Community health	4	50	88	38	8	54	50	-4	42	28	56	NA
Social work	4	53	82	29	5	40	44	4	25	6	41	NA
Medical practitioner	9	51	75	24	10	44	42	-2	26	13	40	.004
Overall services score	9	48	78	30	10	43	43	0	30	23	37	<.001

Continued on following page

Notes to Table B

Some of the service elements were only applicable and evaluated in the higher-level hospitals, so comparison between intervention and control arms was not appropriate due to the small sample size. For completeness the results are included.

One large hospital in the intervention group was given permission to postpone its external evaluation, so its results were not available. For comparative purposes the baseline value of this hospital was also excluded from the results of the table, leaving only nine hospitals in each group. Each hospital included in the calculations, therefore, has a baseline and external value from which the change scores were calculated (External–Baseline).

The mean change in scores in the control hospitals reflects very little change and the random variation (+ values versus – values) reflects the consistency of the results. The change in scores calculated over the services elements in the intervention arm reflects a consistent improvement, even in the elements with small numbers of hospitals.

The baseline mean values over the services elements are comparable between the two arms of the study, probably due to the stratified randomization of the hospitals at the start of the accreditation process.

NA = Data not available.

Table C
Quality Indicators Proposed by Workshop Participants (May 1999)

Indicator (Organized by Type)	Determined Infeasible by Workshop	Determined Infeasible in Testing	Retained for First Round
Surgical and Obstetrical/Gynecological			
Completeness of various sections of the peri-operative notes			X
Mean elapsed time for abdominal and thoracic trauma, from time of arrival in casualty to time of arrival in theater			X
Mean number of days from date of admission to date of elective surgery			X
Number of stillbirths and neonatal (<28 days old) deaths / Total number of deliveries			X
Repeat surgery within 30 days / Total operations in theater		X	
Number of maternal deaths/ Total number of deliveries		X	
Number of C/S cases converted from spinal to general anesthesia	X		
Number of pre-anesthesia assessments adequately completed by a nurse/ Total number of surgical cases	X		
Number of anesthesia assessments adequately completed by an anesthetist/ Total number of surgical cases	X		
Unscheduled post-operative ICU admissions	X		
Accidental extubation	X		
Post-operative mortality rate	X		
Prolonged recovery from anesthesia	X		
LOS for various surgical conditions	X		
Glasgow coma scale completed in head injury patients	X		
Post-operative mortality rate	X		

Continued on following page

Table C
Quality Indicators Proposed by Workshop Participants (May 1999) *(Continued)*

Indicator (Organized by Type)	Determined Infeasible by Workshop	Determined Infeasible in Testing	Retained for First Round
Management and Administration			
Patient satisfaction			X
Nurse perceptions and satisfaction			X
Financial planning			X
Hospital sanitation*			X
Needle-stick injury rates	X		
Time between needle-stick injury and commencement of prophylactic treatment	X		
Absenteeism rate	X		
Medical (Including Pediatrics, Laboratory and Pharmacy)			
C/S wound infection rate			X
Medical record completeness: surgical, medical, and pediatric (maternity excluded due to standardized forms)			X
Medical record accessibility and correct delivery			X
Patient education regarding medicines			X
Labeling of ward stock medicines: ID, batch number, and expiration date			X
Patient waiting times for medicines	X		
Correct labeling of laboratory specimens and completeness of request form	X		
Correct labeling of X-ray films, completeness of request form and report availability	X		
Childhood mortality rate for gastro-enteritis (excluding HIV infection)	X		
Mortality rates	X		
Number of repeats for the same lab test	X		
Number of repeats for the same X ray	X		

Notes: C/S = cesarean section; ICU = intensive care unit; LOS = length of stay; ID = identification

* Added by researchers after indicator workshop.

Participants at Research Indicator Development Workshop, May 1999: Ms. Petro de Beer, Dr. David Boonzaier, Dr. Derek Burns, Dr. Clive Daniels, Prof. Ronald Green-Thompson, Dr. John Heavens, Dr. Helga Holtz, Dr. Carl J Lombard, Dr. Ivan McCusker, Dr. Marie Muller, Dr. Humsa Naidoo, Dr. Busi Nyembezi, Mr. David Nzanira, Ms. Anne Rooney, Dr. Jack Salmon, Dr. Giel van Schalwyk, Ms. Jerry Sharp, Ms. Anna Marie van der Walt, and Dr. Stuart Whittaker.

Table D
Quality Indicator Scores of Intervention and Control Hospitals over Time

Indicator	Intervention (N=10)			Control (N=10)			95% Confidence Limits			
	Mean Time 1 (SD)	Mean Time 2 (SD)	Mean Change (SD)	Mean Time 1 (SD)	Mean Time 2 (SD)	Mean Change (SD)	Mean Intervention Effect	Lower	Upper	P-Value
Nurse perceptions										
Clinical subscale	75.1 (8.9)	76.6 (7.8)	1.5 (8.0)	77.6 (10.0)	70.8 (10.9)	-6.8 (10.9)	8.2	0.4	16.1	.040
Teamwork subscale	71.0 (8.2)	71.8 (5.4)	0.8 (6.7)	71.0 (9.7)	67.0 (8.0)	-4.0 (6.7)	4.8	-1.0	10.6	.097
Participation subscale	52.8 (8.9)	54.8 (6.3)	2.0 (8.9)	53.6 (13.4)	49.2 (11.4)	-4.4 (10.7)	6.4	-2.8	15.8	.158
Overall score	59.3 (6.1)	60.8 (4.4)	1.5 (5.1)	60.8 (8.1)	56.5 (6.3)	-4.2 (6.7)	5.7	0.6	10.9	.031
Patient satisfaction	86.9 (5.0)	91.5 (2.4)	4.6 (5.0)	87.0 (6.0)	90.1 (2.2)	3.1 (4.6)	1.5	-2.8	5.7	.484
Medical education	42.9 (5.2)	43.1 (6.3)	0.2 (4.7)	41.5 (10.0)	40.0 (9.9)	-1.5 (3.9)	1.7	-2.5	5.9	.395
Medical records: accessibility	85.4 (9.0)	77.5 (9.0)	-7.9 (9.4)	79.4 (13.6)	68.4 (17.0)	-11.0 (9.6)	3.1	-6.1	12.2	.492
Medical records: completeness										
Admission elements	52.5 (11.1)	55.3 (9.7)	2.8 (7.6)	52.8 (7.1)	50.1 (7.8)	-2.7 (8.2)	5.5	-2.4	13.4	.136
Discharge elements	39.2 (7.8)	39.9 (8.3)	0.8 (10.8)	42.4 (3.4)	37.2 (7.6)	-5.2 (7.8)	6.0	-2.2	14.1	.173
Overall score	47.1 (7.7)	49.1 (7.1)	2.0 (7.7)	48.6 (5.0)	44.9 (7.0)	-3.7 (7.4)	5.7	-1.4	12.9	.114
Completeness of peri-operative notes										
Pre-operative record	63.2 (6.7)	64.8 (6.1)	1.6 (4.5)	60.3 (3.8)	62.3 (3.8)	2.0 (1.6)	-0.4	-4.1	3.6	.887
Anesthetic record	83.2 (7.1)	82.2 (9.6)	-1.0 (5.0)	75.1 (8.1)	78.7 (5.3)	3.6 (7.8)	-4.6	-11.4	2.2	.172
Operation record	68.4 (14.3)	76.8 (18.0)	8.4 (10.9)	70.8 (20.6)	78.2 (19.0)	7.4 (14.0)	1.0	-12.7	13.7	.938
Overall score	70.2 (5.4)	72.7 (8.0)	2.5 (5.5)	65.2 (9.2)	69.6 (7.5)	4.4 (6.5)	-1.9	-8.4	4.3	.489

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Table D
Quality Indicator Scores of Intervention and Control Hospitals over Time *(Continued)*

Indicator	Intervention (N=10)			Control (N=10)			95% Confidence Limits			
	Mean Time 1 (SD)	Mean Time 2 (SD)	Mean Change (SD)	Mean Time 1 (SD)	Mean Time 2 (SD)	Mean Change (SD)	Mean Intervention Effect	Lower	Upper	P-Value
Ward stock labeling	66.0 (23.2)	81.8 (9.3)	15.8 (19.3)	45.6 (31.3)	49.6 (25.2)	4.0 (22.0)	11.8	-3.1	26.7	.112
Hospital sanitation										
Soap available	41.9 (17.4)	43.6 (23.1)	1.7 (14.1)	36.4 (22.8)	35.1 (20.5)	-1.3 (21.5)	3.0	-14.1	20.2	.713
Water running	91.3 (12.1)	99.4 (1.8)	8.1 (12.7)	81.6 (16.5)	97.5 (3.3)	15.9 (14.2)	-7.8	-20.3	5.0	.218
Toilet clean	56.7 (24.2)	62.8 (22.3)	6.1 (18.1)	48.0 (26.8)	60.5 (24.3)	12.5 (20.2)	-6.4	-24.4	11.6	.462
Overall score	59.7 (17.4)	62.8 (15.5)	3.1 (12.4)	50.2 (17.1)	55.7 (14.7)	5.5 (9.3)	-2.4	-5.7	12.0	.641

The sample size for each group is 10 hospitals except for (a) medical records retrieval and accuracy (one intervention hospital excluded as a known outlier; none of its records were retrieved at Time 1), and (b) completeness of peri-operative notes (two control hospitals could not provide baseline data).

The scale used for all the indicators is the mean percentage.

Subscales of certain indicators are given for completeness.

A positive value for the intervention effect indicates a benefit due the intervention whereas a negative value indicates the opposite.

The confidence intervals and p-values were obtained from an analysis of variance model with experimental group and stratum as the main effects.

SD = standard deviation.



Commentaries

Commentary by Stuart Whittaker,⁹ Marie Muller,¹⁰ and Marilyn Keegan¹¹

Acknowledgements

Acknowledgements are due to the following people who helped compile this commentary:

Editing—Carol Balchin; Data extraction—Val Dekenah and Saskia Blakeway; Graphs—Gill Eames; and researchers at the South African Medical Council who read and participated in this commentary.

I. Introduction

This study was unique because it attempted to evaluate the impact of a facilitated accreditation process on under-resourced hospitals, many with poor physical infrastructures and operating in a climate of political transformation. To date, no studies in South Africa have used performance indicators to measure the impact of accreditation on hospitals, which have not only been severely compromised by the apartheid regime but are also coping with the HIV/AIDS epidemic.¹²

This review of the research in KwaZulu-Natal Province elucidates several aspects of the study:

- The COHSASA data collection and analysis process,
- Management commitment as a possible factor in the gain in hospital performance,
- The changes in compliance with the accreditation standards, and
- The indicators chosen to measure the impact of the accreditation program.

The following documents were reviewed in order to evaluate the research methods and results achieved:

- Contracts entered into by the parties involved in the research,
- Minutes of steering committee meetings,
- Research assistants' reports completed after each hospital visit,
- Guidelines given to research assistants,
- Research reports,
- The accreditation standards used in the study, and
- Standard compliance data captured at the baseline and external survey stages of the

Facilitated Accreditation Programme (FAP).

II. COHSASA Data

COHSASA facilitators visited the ten intervention hospitals regularly and assisted the hospitals to conduct baseline surveys, use the reports generated to prioritize improvements necessary to meet the required standards, and teach staff how to use quality improvement techniques to do so. Only baseline and external surveys were conducted at the control hospitals, and these were planned to coincide with those of the intervention hospitals.

Figure 1 shows the measurement system COHSASA used to assess the compliance of the hospitals against the accreditation standards.

The criteria (measurable elements) used by COHSASA can be scored as compliant, partially compliant, or not compliant, and scores are awarded for each category. If a criterion is scored as compliant, it is scored as 100; if not, amounts are subtracted as determined by the seriousness of the deficiency according to the weighting system shown in Table 1.

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¹¹ M. Keegan is Communications Manager for COHSASA.

¹² Dorrington RE, Bradshaw D, and Budlender D. 2002. HIV/AIDS Profile of the Provinces of South Africa—Indicators for 2002. Cape Town: Centre for Actuarial Research, Medical Research Council and the Actuarial Society of South Africa.

Figure 1
Measurement System Used to Assess Standard Compliance

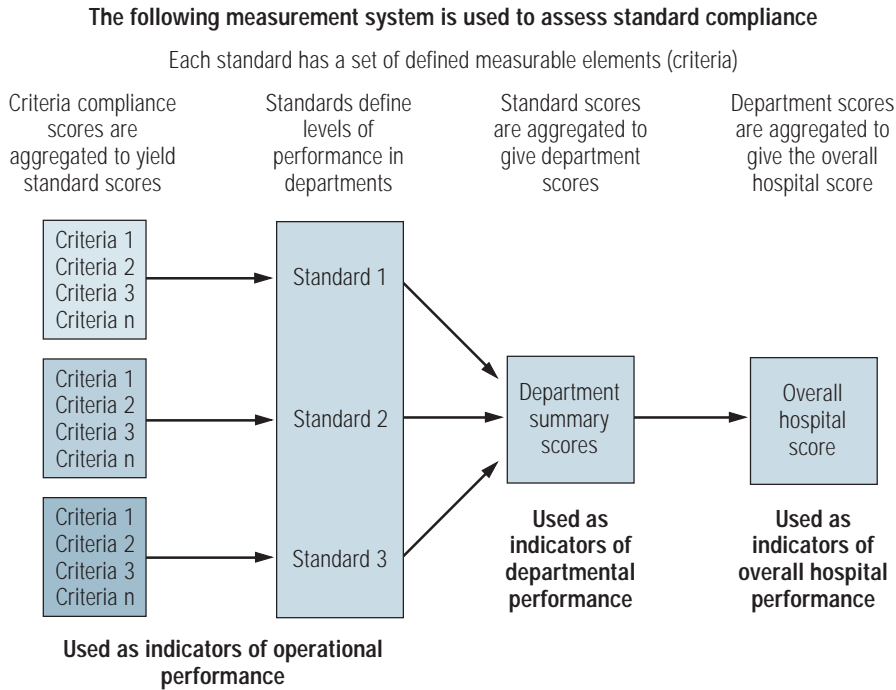


Table 1
COHSASA Scoring Criteria

Partial Compliance (PC)	Severity	Score
PC	Mild	75
PC	Moderate	65
PC	Serious	55
PC	Very serious	45
Non-Compliance (NC)	Severity	Score
NC	Mild	35
NC	Moderate	25
NC	Serious	15
NC	Very serious	5

Figures 2 and 3 show the overall hospital compliance scores achieved in the two sets of hospitals at the baseline and external survey phases of the program.

Figure 2
Control Hospitals: Overall Scores with No QI (Quality Improvement) Program

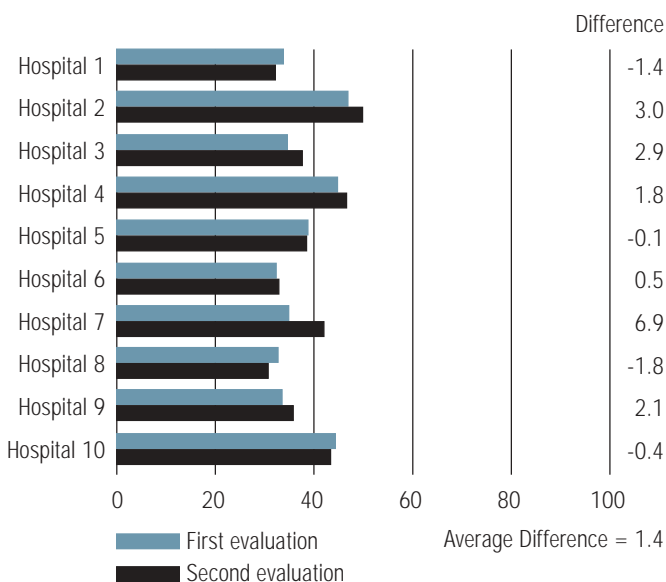
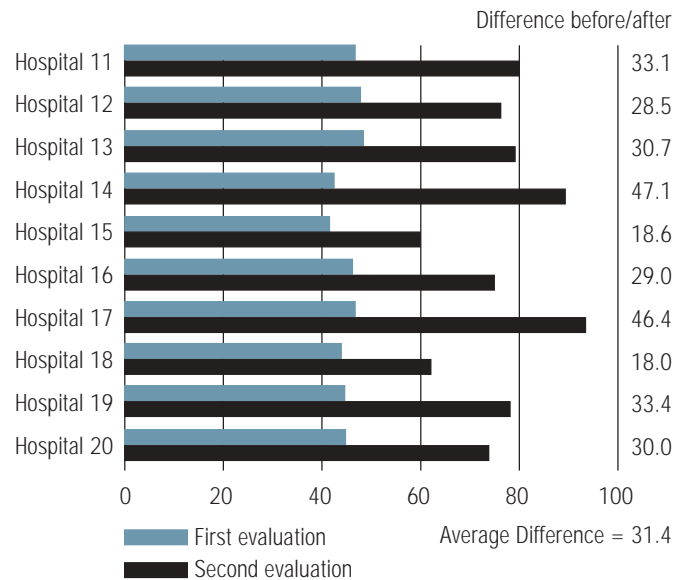


Figure 3
Intervention Hospitals: Overall Scores with QI (Quality Improvement) Program



All intervention hospitals made noticeable progress towards meeting the accreditation standards. There was very little improvement in control hospitals. Thus, it is likely that the FAP brought about the difference between the two groups.

Figure 3 shows that there is a wide difference in the overall compliance scores of the intervention hospitals in the second evaluation, ranging from 59.9 in hospital 15 to 93.1 in hospital 17, with an average score of 76.6.

COHSASA requirements for full accreditation are:

- Services must achieve substantial standard compliance; that is, all services must have a compliance score of at least 80/100.
- Remaining non-compliant (NC) and partially compliant (PC) criteria must not pose a risk to patient and staff safety or contravene legal requirements.

For this reason, only one intervention hospital and no control hospitals had met the requirements for accreditation at the time of the external surveys conducted during June and November 2000. Recent analyses carried out by COHSASA have found that all hospitals that have met COHSASA's accreditation criteria have achieved scores > 93.

Further analysis has been, and is being, carried out by COHSASA (unpublished data). The unavailability of resources and state of disrepair of the facilities make it difficult for hospitals to improve without dedicated intervention. Hospitals with poor hospital and technology maintenance programs have difficulty in improving these areas. Hospital maintenance services, for example, struggle to bring about

improvements not only due to limitations within their own domain, such as staff skills, but also due to the failure of external authorities to provide a timely service.

Hospitals, however, are generally able to improve clinical areas within 12 months, provided that a basic staff infrastructure exists. However, it is challenging for hospitals to develop and implement evaluation programs, such as nursing and clinical audit. Improving management is also difficult without commitment from both the hospital and controlling authorities.

III. Management Commitment as an Explanatory Variable

In the study, hospitals were randomly selected and there were thus few opportunities to hold workshops prior to the commencement of the program in order to obtain their commitment. As the program progressed, facilitators who had worked for the hospitals for two years identified three hospitals with differing degrees of management commitment to the COHSASA FAP. In one hospital, management showed poor levels of commitment. In another, management became very supportive midway through the program, while in the third hospital management showed early support and commitment to the program.

The overall service and departmental compliance scores at baseline and external surveys are shown for the three levels of management commitment: low (Figure 4), late (Figure 5), and good (Figure 6).

These results suggest that management participation may be an

important factor in disadvantaged hospitals working towards compliance with accreditation standards.

IV. Low Quality of the Research Data May Have Biased the Results

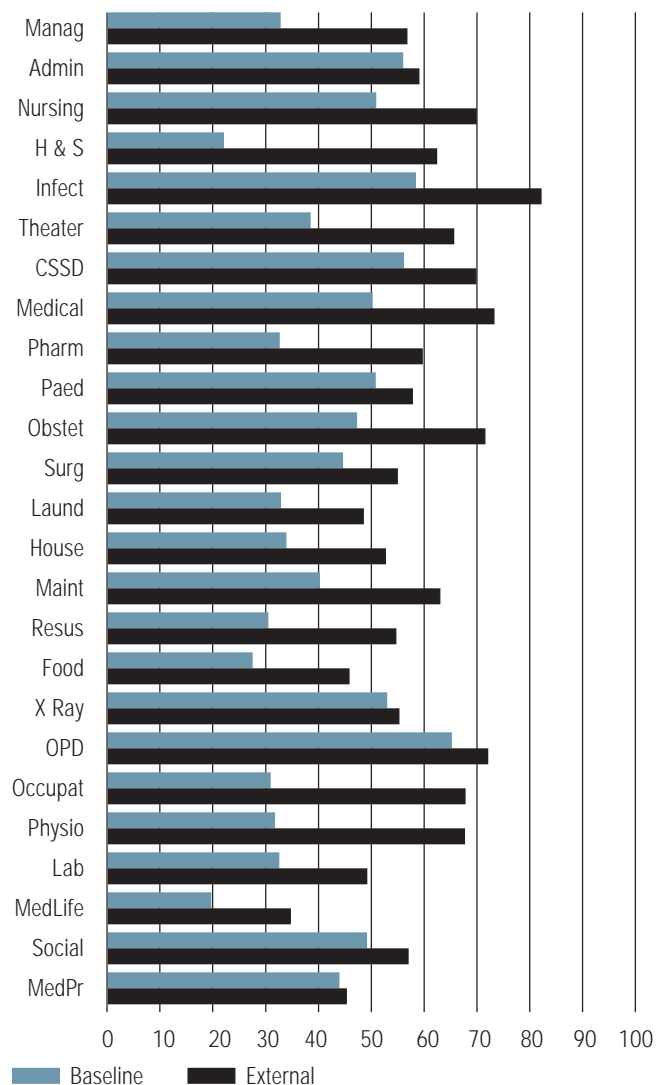
There are several overall factors that reduced the quality of the research data, categorized here under "time frame," "funding delays," "inadequate planning," "limited number of research indicators," "limited testing," and "inadequate communication." These factors are described below along with the impact they had on the data.

Time Frame

In 1998, negotiations were started with the KwaZulu-Natal (KZN) Department of Health to enter 29 of its 56 hospitals in the COHSASA FAP, and a contract was signed that November. Since accreditation was new to the province, the possibility of researching the impact of accreditation via a randomized control trial was very attractive. The proposed research project was discussed with the province and the Medical Research Council (MRC) of South Africa, and both parties agreed to participate if funds were forthcoming.

There was, however, limited time to prepare for the research because, according to the contract, work was to start in the 29 contracted hospitals in December 1998. On the understanding that research funding would be secured, COHSASA obtained the assistance of the MRC to select an intervention and a control group of hospitals in preparation for the proposed research. A random sample of 10 intervention

Figure 4
Before/After Overall Departmental Compliance Scores in a Hospital with Low Management Commitment

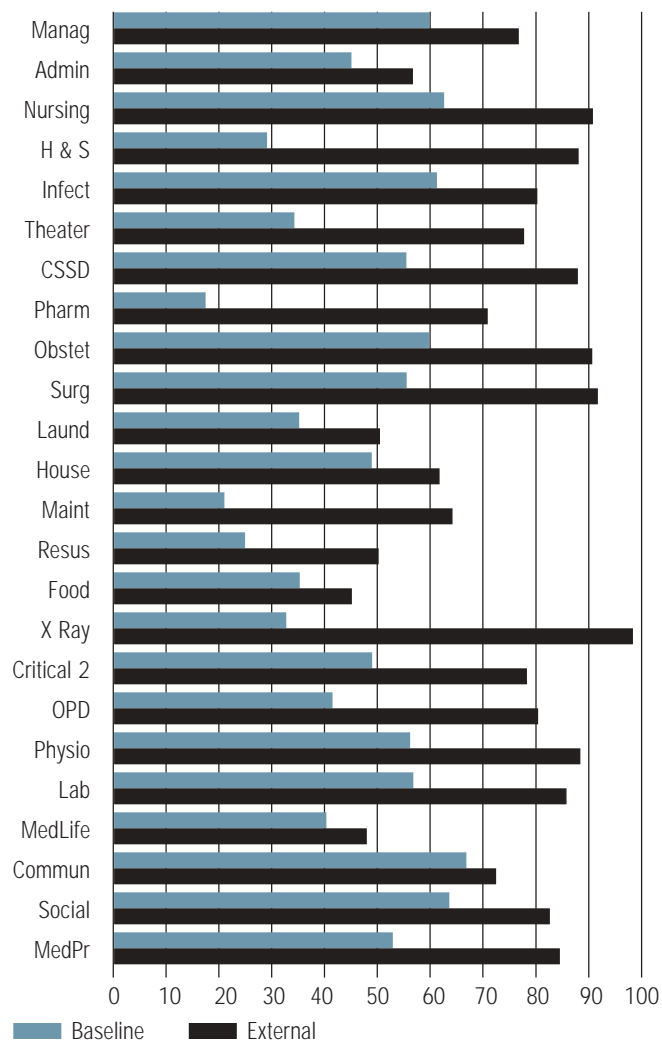


Note: Average overall scores improved from 41.4 to 59.4 (18 points) in 25 selected measurement areas.

and 10 control hospitals was selected, and the FAP was set up so as to include the intervention hospitals and exclude the control hospitals. Since it is COHSASA's policy to evaluate the effectiveness of its programs on an ongoing basis, it was determined that the opportu-

nity offered by this research should not be lost, so baseline surveys of the control hospitals were conducted at COHSASA's expense to allow comparison of the two groups of hospitals to be made from the start of the FAP.

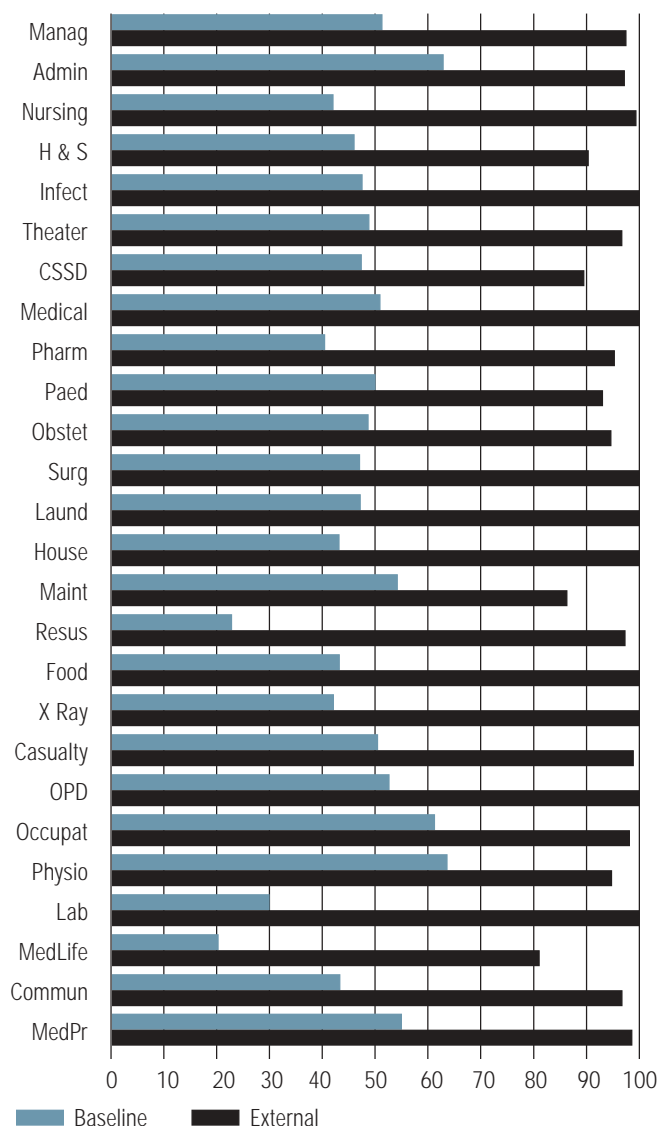
Figure 5
Before/After Overall Department Compliance Scores in a Hospital with Late Management Commitment



Note: Average overall scores improved from 45.9 to 74.9 (29 points) in 24 selected measurement areas.

COHSASA, with the assistance of Joint Commission Worldwide Consulting (JCWC), approached the Quality Assurance Project (QAP) of the Center for Human Services towards the end of 1998 to fund the research project. The research proposal recommended that the

Figure 6
Before/After Overall Departmental Compliance
Scores in a Hospital with Good Management
Commitment from the Start



Note: Average overall scores improved from 46.5 to 96.2 (49.5 points) in 26 selected measurement areas.

process be overseen by a steering committee consisting of one or two representatives from KwaZulu-Natal, one from QAP/JCWC, one from the

time as the standard evaluations and a third during the FAP. The FAP baseline surveys were conducted from December 1999 to February

MRC, and one or two from a technical advisory group, which was to be appointed. This committee was to meet once or twice per year as the study progressed. The research team consisted of two co-principal investigators (one from the U.S. and one from South Africa), a statistician, four research assistants, and one data entry clerk.¹³

There were two elements to the research. The first evaluated changes in compliance with accreditation standards at the beginning and end of the FAP. The second developed several research performance indicators to be measured at three points during the FAP: two at the same

2000, and it was hoped to conduct the first indicator data collection at approximately the same time.

Every effort was made by all parties to expedite the research funding. QAP issued a letter of intent in May providing US\$ 15,000 to cover the costs of a steering committee meeting in Cape Town and an indicator development workshop in Durban. Those events took place as soon as notification was received. In September 1999 a second letter of intent from QAP provided funds for the indicator data collection. The uncertainty surrounding the funding of the research had a major impact on the research design, its implementation, and the research activities as described below.

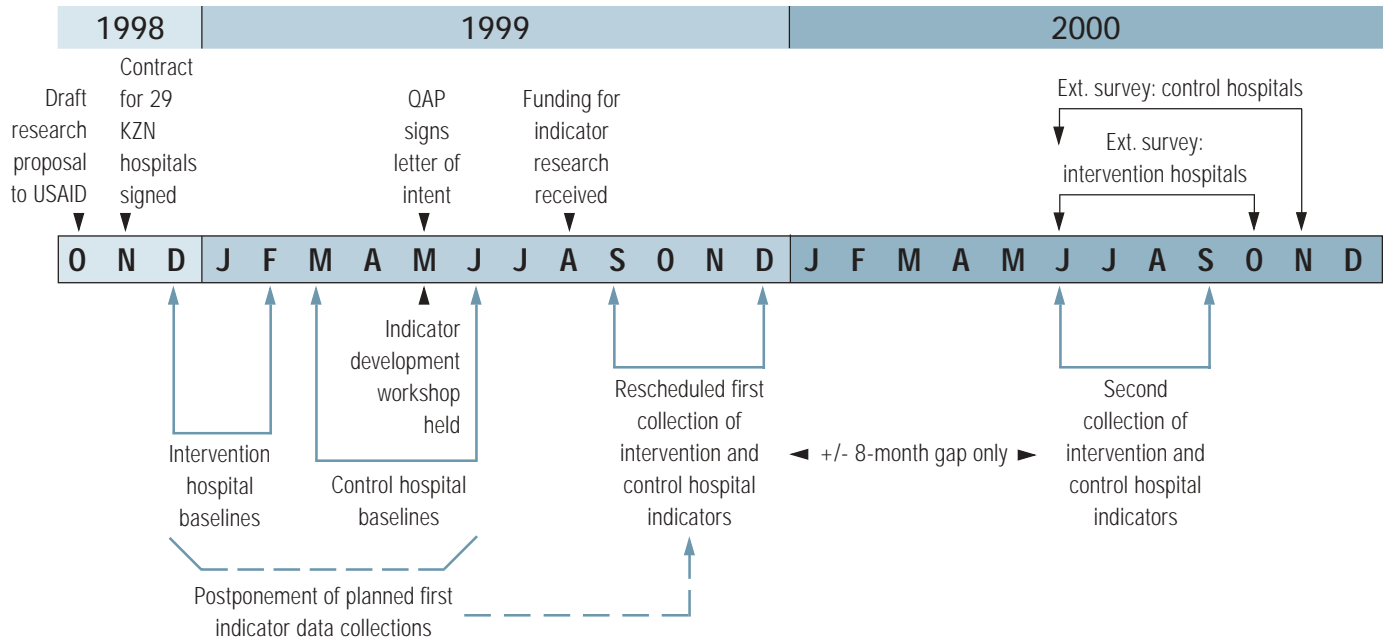
Funding Delays Affected the Research Design

The complexity and time required to develop, pilot, modify, and implement reliable performance indicators were largely underestimated and had to fit into the time frame stipulated by the contract between KZN and COHSASA. This was compounded by the delayed start of the indicator development process.

Originally, it had been planned to develop research indicators at the start of the program (December 1998), make initial measurements of them at about the same time as the baseline COHSASA accreditation standards, make interim measurements partway through the program, and complete the third and final measurement of the research indicators about 18 months after the initial measurement. However, the delay in funding caused a delay in

¹³ The South Africa-based co-principal investigator moved about two-thirds of the way through the project, and a South Africa-based researcher substituted for the tasks requiring a South African residency.

Figure 7
Summary of Project Timelines



the start of the development of the research indicators until June 1999 and their completion in September 1999 (nearly four months later). The initial measurement of the research indicators took place in September–October (approximately nine months after the baseline COHSASA accreditation standards measurement); the interim measurement of research indicators was dropped; and the final measurement of research indicators occurred in June–September 2000 (on-average only 8.5 months after the initial measurement of research indicators). (See Figure 7.)

Inadequate Planning Caused Data Acquisition Problems

Planning is a critical process in any research operation, particularly one with severe time constraints as in this case. The indicator data collection process was understandably detrimentally affected by lack of detailed planning. The problem was exacerbated by having to travel long distances between hospitals on very bad roads.¹⁴ At one hospital, the research assistants found that they had nowhere to stay despite having been told beforehand that accommodation had been arranged. They

were eventually accommodated in staff lodgings, but were not provided with meals.¹⁵

Planning was based on unverified hospital information. For example, in one hospital, the official bed status had been cited as 296, but this was subsequently found to be incorrect, with, in fact, 400 to 450 patients being accommodated at that time. This resulted in much greater workloads for the research assistants than had been anticipated.¹⁶

Research assistants were sometimes required to work a 16-hour day.¹⁷ It is possible that frustration and exhaustion may have influenced

¹⁴ Research Assistant (RA) Reports 1, Report from Research Team for SAAIRP, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>. [Note: These web pages have restricted access–Ed.]

¹⁵ RA Reports 5, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00005.html>. [Restricted access]

¹⁶ RA Reports 5, <http://www.healthnet.org.za/mrcgroups/saairp/msg00005.html>. [Restricted access]

¹⁷ RA Reports 1, Edendale Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>. [Restricted access]

the level of their efficiency and therefore the reliability and accuracy of the data collected. Eventually, the research assistants asked for a discussion on the future layout of the indicator collection.

The research assistants tried to overcome time constraints by working on Saturdays, but they found this of little value because the hospital routine was such that few patients were available for interviews. This situation arose because the doctors first completed ward rounds and attended to emergencies before visiting the outpatient department, and by this time on a Saturday the pharmacy would be closed. In three and a half hours at the hospital, the research assistants were able to interview only two patients.¹⁸

The lack of effective planning also unfavorably impacted the time available for hospitals to prepare for their accreditation surveys. In seven of the ten intervention hospitals, the second indicator collection was carried out before the accreditation surveys—when the appropriate time would have been a few days *after* the external survey.

In four of these hospitals the indicator data collection visits took place from six to 34 days before the scheduled accreditation surveys when the hospitals were actively preparing for the external peer review. This caused extra strain on the hospitals because they were required to attend to the requests of indicator research assistants at the same time as they were putting the

finishing touches on preparations for their accreditation visits. One medical superintendent commented that the timing of the COHSASA external survey and the second data collection for the indicators had placed staff under extra pressure¹⁹ and expressed concern about the quality of data the research assistants were receiving due to this pressure.²⁰

Three of the hospitals had research indicator collections more than two months before the external survey, with one being eight months before. In such cases it is unlikely that the second research indicator collections would accurately reflect conditions in the hospitals when the external accreditation surveys were carried out only about eight months on average after the initial research indicator measurements. Ideally, there should have been a further collection of research indicator data to coincide with the external accreditation survey.

Limited Number of Research Indicators

It was not possible to test the quality of the research indicators prior to their use because of the time limitations. As a result, after reviewing the results of the first indicator data collection process (about three-quarters of the way into the study), four of the original 12 indicators were dropped. The eight indicators finally used in the study appeared to be chosen because of the ease of data collection and convenience.

Three of the indicators focused on medical record administration (4, 5, 6), two on pharmacy (3 and 7), one on housekeeping (8), and one on nursing management (1). The eighth indicator (2) focused on patient satisfaction. Because surgeons were not consulted, indicators 4, 5, and 6 were essentially an evaluation of the efficiency of medical record administration rather than of the content of the record. This is illustrated in Figure 8 except for the patient satisfaction indicator.

Limiting the number of indicators meant that the impact of the accreditation program was not evaluated in clinical services, clinical support areas (other than pharmacy), technology support services, or hotel services (other than housekeeping). Furthermore, even in those areas assessed, the indicators only evaluated a small component of each service area/ department. Figure 8 clearly shows that the system of research indicators could evaluate only a minimal aspect of FAP's total potential impact.

Limited Testing Used by the Research Assistants

The training of research assistants, testing of indicators, and data collection methods were piloted in a large urban hospital and a peri-urban hospital. The researchers anticipated that this would be sufficient to enable the research assistants to implement the indicator research component in the rural hospitals. This may be the reason

¹⁸ RA Report 5, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>. [Restricted access]

¹⁹ RA Reports 5, Eshowe Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00020.html>. [Restricted access]

²⁰ RA Reports 5, Eshowe Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00020.html>. [Restricted access]

why the senior researchers relied on telephone communication with research assistants to manage difficulties in rural hospitals should they arise.

However, the failure to validate the research methodology in rural hospitals had a significant impact on the data-gathering process, as shown in the examples below. The hospital information sheet for the first

research indicator collection asserts that data gathering involving nurses filling in a questionnaire that “will take about 5 to 7 minutes.” However some hospitals took 45 minutes²¹ for nurses to complete the questionnaire, and in one hospital research assistants found that nurses were unable to complete questionnaires even within four hours.²² In most cases this was due to the nurses’ heavy workload,²³ staff shortages, and an attitude of non-cooperation.²⁴ These factors led to poor staff participation and support. In one hospital ward, only five nurses out of a staff of 35 agreed to participate.²⁵

These factors meant that research assistants were frequently rushed. In addition, difficulties experienced in reaching the co-principal investigator by telephone led on occasion to research assistants coping with problems themselves. For example,

²¹ RA Reports 1, Eshowe Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/maillist.html/msg00001.html>. [Restricted access]

²² RA Reports 1, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/maillist.html/msg00005.html>. [Restricted access]

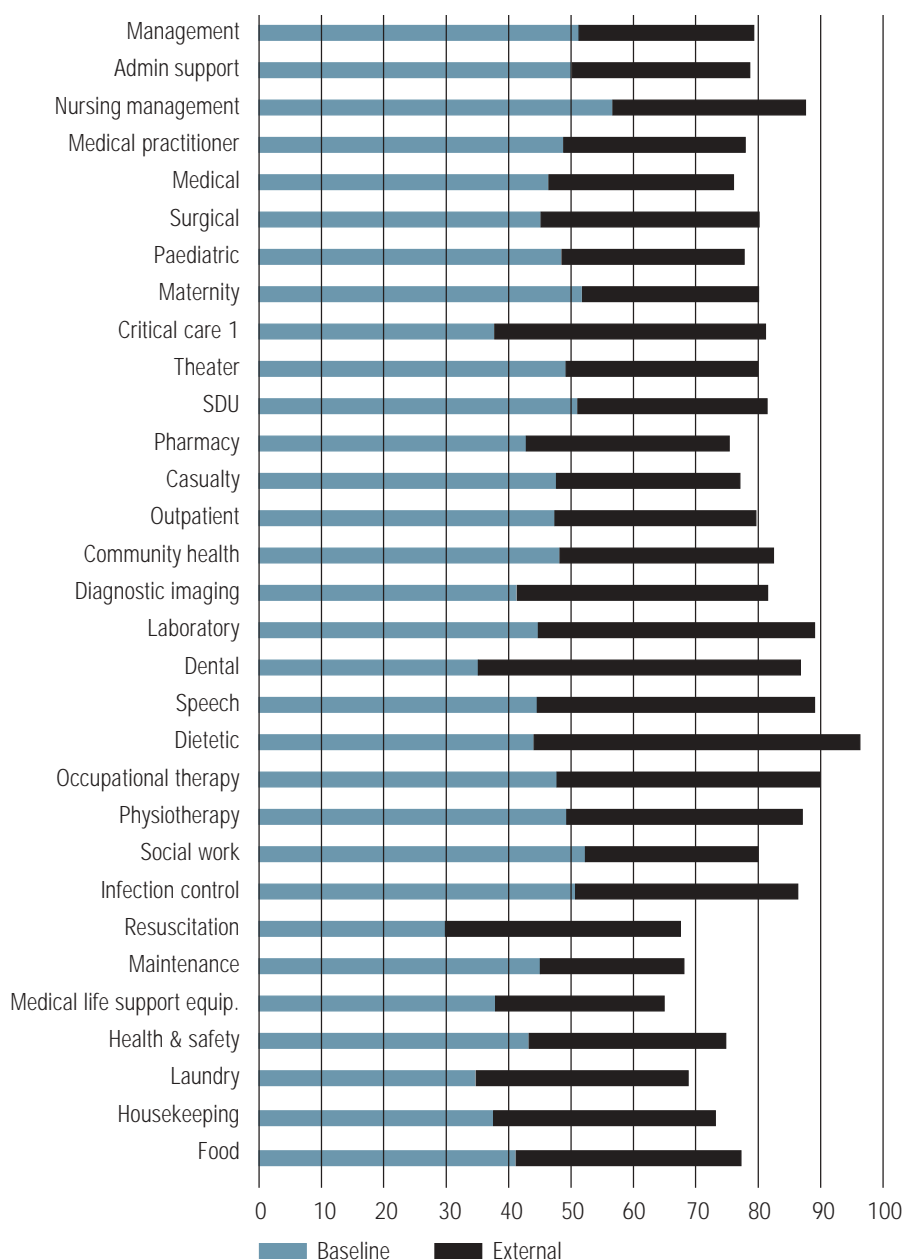
²³ RA Reports 1, Edendale Hospital 04-Intervention, <http://www.mrc.ac.za/services/discussions.htm>, Lower Umfolozi District War Memorial Hospital 10, <http://www.healthnet.org.za/mrcgroup/saairp/msg00002.html>. [Restricted access]

²⁴ RA Reports 1, Grey’s Hospital Intervention, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>. [Restricted access]

²⁵ RA Reports 4, Benedictine Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg0004.html>. [Restricted access]

Figure 8

KZN Intervention Hospitals Overall Service/Department Scores



in one hospital where registers appeared to have been misplaced, a research assistant who had difficulty retrieving files was unable to reach the co-principal investigator to obtain guidance.²⁶

Inadequate Communication between Hospitals and Researchers

In a project of this magnitude, good communication with hospitals is essential to ensure that hospital staff are fully informed of the reasons for the research so that, among other reasons, they cooperate with research assistants in obtaining the required research data. Although hospitals were sent letters and faxes to inform them of the research and its aims and to schedule the intended visit, internal communication problems at the hospitals resulted in faxes not being passed on or information not being relayed to managers. This may explain why—in several instances—information did not reach relevant members of hospital staff who were required to assist with the research process and/or provide research data.

Perusal of the research assistants' reports reveals many problems from this mis-communication. Sometimes, hospitals were not expecting researchers or were ill prepared to receive them and had not made

concrete plans for their accommodation.²⁷ Departments had to make last-minute arrangements to accommodate them and to find time to locate documents, complete various questionnaires, and supply the information required.²⁸ Because they had not been clearly informed of the research assistants' visits, hospital staff were sometimes defensive and uncooperative; and, on occasion, the research assistants could not proceed without the help of the hospital manager. Lack of co-operation from hospitals made the process of data gathering by the research assistants very difficult and laborious.²⁹ There were also delays because some medical superintendents did not arrive for pre-arranged appointments. This led to frustrations on the part of both hospital and research staff and reduced the time available for data gathering.

The hospital information sheet issued by the co-principal investigator requested hospitals to ensure that various registers (theater registers and adult and pediatric ward registers) could be retrieved and made available to research assistants on arrival because testing had shown that finding them could be very time-consuming. Hospitals either did not take this request seriously or the process lacked follow-up because research assistants encountered several problems.³⁰

When the second indicator data were collected, research assistants took the initiative to confirm visits with hospitals by telephone, i.e., they followed up previous letters and faxes sent to hospitals. This improved staff co-operation in hospitals.

V. Comparing Research Indicators to the Most Closely Associated COHSASA Standards

COHASA sets standards that define the systems required for the efficient management of departments and services and the provision of quality patient care. These standards are, in turn, defined by measurable elements (criteria).

For all eight research indicators, COHSASA selected a subset of COHSASA measurable elements that corresponded most closely to the research indicator selected by the researchers. The majority of the selected COHSASA measurable elements were slightly "upstream" from the corresponding research indicator (i.e., most COHSASA measurable elements had impact before the point in time when the research indicator was measured) and could be expected to rise and fall with the research indicator, assuming lack of bias in measure-

²⁶ RA Reports 5, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00005>. [Restricted access]

²⁷ RA Reports 1, Catherine Booth Hospital, Edendale Hospital, Grey's Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00001>; RA Reports 2, Lower Umfolozi District War Memorial Hospital <http://www.healthnet.org.za/mrcgroups/saairp/msg 00002>; RA Reports 3, RA Reports 5, Prince Mshiyeni Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00003>. [Restricted access]

²⁸ RA Reports 5, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00005>. [Restricted access]

²⁹ RA Reports 2, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00002>, Lower Umfolozi District War Memorial Hospital, RA Reports 5, Prince Mshiyeni Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00005>. [Restricted access]

³⁰ RA Reports 5, GJ Crookes Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg 00005>. [Restricted access]

Table 2
Comparison of All Eight Research Indicators with COHSASA Proximate Clusters
across Hospitals and Surveys

Research indicators	Intervention Hospitals				Control Hospitals			
	Research Indicators		COHSASA Proximate Clusters		Research Indicators		COHSASA Proximate Clusters	
	1st	2nd	Baseline	External	1st	2nd	Baseline	External
	Nov. 1999	Aug. 2000	Jan. 1999	Aug. 2000	Nov. 1999	Aug. 2000	Mar. 1999	Aug. 2000
#1. Nurse perceptions	57.3	60.8	57.0	83.5	60.8	56.5	54.1	56.8
#2. Patient satisfaction	86.9	91.5	41.1	75.4	87.0	90.0	37.3	43.4
#3. Medication education	42.9	43.1	49.6	70.8	41.5	40.0	48.6	46.4
#4. Medical record access	85.4	77.5	48.7	63.2	79.4	68.4	31.8	23.0
#5. Medical record completeness	45.8	46.4	67.3	73.1	46.7	47.6	50.1	48.8
#6. Peri-operative notes completeness	71.6	74.6	76.7	94.7	68.7	73.1	71.0	64.8
#7. Ward stock labeling	66.0	81.0	25.6	86.6	45.0	49.0	15.3	18.2
#8. Hospital sanitation	59.7	62.8	50.8	75.8	50.2	55.7	52.4	50.7

ment. We refer to the COHSASA subsets of measurable elements as "COHASA proximate clusters," with each cluster corresponding closely to one of the eight research indicators. The COHSASA proximate clusters range from three ("medical record access") to 27 measurable elements ("medical record completeness"). (The appendix, page 43, has a complete list of COHSASA measurable elements making up each proximate cluster.)

The COHSASA proximate clusters were scored according to the levels of compliance measured at the baseline and the external surveys. The average score for each proximate cluster was compared in turn to the first and second research indicator scores. The gains (or lack thereof) of the research indicators

are compared to that of the COHSASA proximate clusters in Table 2 and are discussed in the following pages. The discussion below relies on the data presented in Table 2 and the appendix. The results differ widely by indicator.

Other factors considered were patient co-operation, staff co-operation, data retrieval methods, socioeconomic factors, and environmental factors that may have influenced the research.

Indicator 1: Nurse perceptions of clinical quality, participation, teamwork

The relevant COHSASA measurable elements that jointly measure whether legal, appropriate, and

effective nursing care is ensured in the medical, pediatric, surgical, and obstetric in-patient services and that correspond to the nurse perceptions research indicator are listed in the appendix.

When the advisory group developed the research indicators, it was recommended that an indicator on *work satisfaction experienced by nursing staff* be developed. A standardized questionnaire/ instrument developed by Stamps and Piedmonte³¹ was recommended, subject to minimal changes in terminology to suit the South African context (such as dollars and post ranks of medical doctors/ superintendents and nursing service managers). This instrument tests work satisfaction with regard to pay, autonomy, task requirements,

³¹ Stamps PL and Piedmonte EB. 1986. *Nurses and work satisfaction: An index for measurement*. Ann Arbor, MI: Health Administration Press Perspectives.

organizational requirements, job status, and interaction. The instrument that was ultimately used by the researchers in the impact study underwent significant changes, both in items (content) and scoring scale.

The time required by the research team to obtain the required data was underestimated (see discussion above) and had concomitant effects on already over-burdened staff and stressed research assistants.

In some instances, hospital management misunderstood the purpose of the research assistants' visits; the perception had been that the research assistants had come to alleviate their hardships by way of an inventory (the questionnaire), and it is possible that nurses would then emphasize their negative perceptions as much as possible.³²

Research assistants reported that in several hospitals, even after explaining to nurses how to fill in the answers and stressing the voluntary and confidential nature of the questionnaire, there were still many incomplete forms. They reported that staff preferred to sign with an X rather than identify themselves and that this might suggest they were reluctant to participate and/or feared victimization.³³

Indicator 2: Patient Satisfaction

It can be seen from Table 2 that the research indicator scores of both the intervention and control hospitals were higher than the COHSASA

proximate cluster. Several factors may explain this.

Many patients came from resource-constrained rural backgrounds where water from a tap and a flush toilet were luxuries.³⁴ Research assistants reported that patients adopted a "happy-go-lucky" attitude and were "satisfied with everything." This attitude, however commendable, did not assist researchers to obtain data that realistically addressed patient concerns.

Although language preferences were accommodated, questions posed in a negative manner confused the patients. Some patients, according to the research assistants, were not totally honest. For example, some reported that their ward was clean when this was obviously not the case. Research assistants sensed that patients were fearful, and it seemed that they thought their answers would affect the care they received.³⁵

Data sources appeared to be a problem because research assistants sometimes struggled to interview patients who had stayed in the hospital more than two days, as stipulated by the research guidelines. Statement 7 of the questionnaire, "Waiting time at this hospital appears to be a problem," confused quite a few patients. They often asked "Where?" and some said that they might be helped more quickly in some sections of the hospital than in others. Research assistants reported that hospital staff were not helpful in guiding them to patients. In one instance, ward nurses

referred them to a ward where patients were not lucid.

This would explain the persistently high research indicator scores in both the intervention and control hospitals. It can be seen that the COHSASA proximate cluster calculated from COHSASA measurable elements scores improved significantly. However, because of the persistently high research indicator scores, this would not have been detected by monitoring changes in the indicator scores. In the control hospitals the COHSASA proximate cluster score remained low throughout the study period.

In the light of the research assistants' reports and the very high rates of patient satisfaction—despite observed poor conditions—this research indicator should be considered as flawed.

Indicator 3: Medication Education

Although the COHSASA proximate cluster showed a significant improvement at the external survey, a similar improvement was not found in the research indicator score. The research assistants' reports provided probable reasons for this.

First, the research assistants reported technical problems and confusion in administering this questionnaire, because they had found inconsistencies in the scale values, probably due to a printing error. They also reported that two separate questions had been

³² Based on interviews with research assistants.

³³ As above.

³⁴ RA Reports 4, Benedictine Hospital, <http://www.healthnet.org.za/mrcgroups/saaip/msg0004>. [Restricted access]

³⁵ RA Reports 1, Edendale Hospital, Intervention, <http://www.healthnet.org.za/mrcgroups/saaip/msg00001>. [Restricted access]

conflated in a single question (Question 11), which meant that respondents often agreed with one half of the question and disagreed with the other half.³⁶

Second, research assistants reported that patients were not totally honest in answering this questionnaire. Patients said they understood how to take their medication, but could not answer correctly when the research assistants momentarily took the medicine away and asked what the medication was for and how often it should be taken.³⁷

Third, directives to research assistants about this indicator stipulated that patients interviewed should be “first script” patients. This was often not possible; sometimes only patients with refill prescriptions were visiting the pharmacy on that day,³⁸ so insufficient first script patients could be found. This was further complicated by the fact that patients often came to hospitals for medicines that had been prescribed by outside doctors or clinics. Sometimes nurses collected medication on behalf of discharged patients, resulting in fewer patients available for interviews. Because patients had to wait so long for medicines, they often went home and sent others to fetch their medicines the next day.

Additional environmental factors also influenced medical education. Patients who often waited for a long time to collect medicines were not

interested in being further delayed by answering research assistants’ questions when their names were called to collect their medicines from the dispensary. Other similar imperatives guided patients’ attitudes to the questionnaires: They had waited all day in a dispensary for medicine and were not willing to “waste any more time” on being questioned, particularly those who had to hurry to catch transport home. Some pharmacies were very congested, and it was difficult for researchers to talk privately to patients. In other hospitals, research assistants had to brave cold and windy conditions to interview patients in situations where there was little or no privacy.

Indicator 4: Medical Record Accessibility and Retrieval Accuracy

For hospitals to function optimally, it is expected that patient record retrieval and accuracy rates exceed 90 percent. The results show that this was never achieved in the study hospitals. Although the COHSASA proximate cluster scores improved from 48.7 to 63.2, a score of 63 indicates that systems required for an efficient, effective hospital health record system were not in place.

An added difficulty was the relationship between the research assistants and medical records departments, which was not always

cordial. The research reports revealed that in some cases, research assistants were not treated with courtesy and record clerks ignored their presence.³⁹ At one hospital, the secretary of the medical superintendent had to retrieve records because the registry clerk, according to the research assistants, was “too busy reading his newspaper.” In one case, a registry clerk refused to help because he was “going home.” This lack of co-operation likely had an impact on the data collection process.

In some cases the selection could not even start because patient registers were not available. For example, at one hospital, research assistants were particularly frustrated because staff could not supply files since the admissions register had apparently been moved to a research center in the town. However, these registers were then found in storerooms about 30 minutes before the records department was due to close.⁴⁰ In another hospital—because of a misunderstanding—staff were not aware that hospital records had been authorized to be made available to researchers and barred access on the grounds that they were “confidential.”⁴¹

The research indicator data collection process did not take into account a rather eccentric habit of some KwaZulu-Natal patients who

³⁶ RA Reports 1, Grey's Hospital, <http://www.healthnet.org.za/mrcgroups/saairp/msg00001>. [Restricted access]

³⁷ RA Reports 1, Edendale Hospital, Intervention, <http://www.healthnet.org.za/mrcgroups/saairp/msg00001>. [Restricted access]

³⁸ RA Reports 2, St. Apollinaris Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00018.html>. [Restricted access]

³⁹ RA Reports 2, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00017.html>. [Restricted access]

⁴⁰ RA Reports 1, Hlabisa Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00004.html>. [Restricted access]

⁴¹ RA Reports 1, Edendale Hospital, <http://www.healthnet.org.za/mrcgroup/saairp/msg00001.html>. [Restricted access]

made record retrieval rather difficult: The patients simply disappeared with their files from the hospital premises to avoid waiting in line and having to pay the next time they came.⁴² In South African public hospitals, patients usually have to pay an income-related fee for the service before they can obtain their treatment folders.

Research assistants often reported that the quota of files could not be reached because of the above factors.

The research design may also have influenced the low retrieval rates. The research protocol required that medical record departments should be contacted prior to the visit and informed that the research assistants would be requesting 150 files. The list of patient records requested was to be compiled from patient registers in medical, pediatric, and surgical wards. The task of the medical record department was to estimate the time required and obtain the correct patient file in the time specified. If this was not achieved, it was assumed that the record retrieval system was not functional and the record was logged as "lost."

If a medical record was not received, the medical record staff were asked if they knew where the record was. If they did not, the record was recorded as lost. Research assistants were not asked to check whether there was a record tracer system in place. No attempt was made to investigate the system itself or to ask other categories of staff, such as doctors or nurses, about the efficiency of the system. Rather, the data collection process

relied totally on the co-operation—or otherwise—of the medical records department.

Indicator 5: Medical Record Completeness

There was little change in the research indicators or in the COHSASA proximate cluster scores across the study period. Both sets of scores are low. This may be a reflection of the comprehensiveness of the indicators and/ or problems with the data gathering methodology.

In many hospitals, patient registers were not available and there were no staff to provide them. There was a lack of communication to hospitals because some staff were not aware that these records should be made available to researchers and barred access on the grounds that they were "confidential."⁴³ The medical records department was asked to supply the selected patient records, which were reviewed to determine whether various admission and discharge data elements had been recorded.

Research assistants reported confusion with certain data-capturing elements in these forms, suggesting that the absence of a patient identification (ID) made it neither a "full" nor an "absent" medical record. They suggested that allowance for minimum/ medium variables should have been applied to this detail, rather than "full" or "absent." Research assistants felt that an ID number was neither useful nor appropriate as a data variable of medical record completeness

because many people in South Africa did not, and still do not, have ID documents.

Indicator 6: Completeness of Peri-Operative Notes

This was a 21-item note audit of 50 files of peri-operative notes that indicated the quality of overall surgical and anesthesia care. The data retrieval methods required that the theater registers be used to identify the medical records of 100 patients who had undergone surgery requiring some form of significant incision and anesthesia. Records were to be obtained from the medical records department.

In the intervention hospitals the COHSASA proximate cluster score improved from 76.7 to 94.7. There was little change, however, in the research indicator scores. Examination of the research assistants' reports provides an explanation for this.

Research assistants noted that the data indicator collection form was designed to examine one particular peri-operative format, viz the Anaesthetic Operation and Recovery Record (AORR). But many doctors—as in the urban hospital where the indicators were tested—did not record their operations, procedures, or closure notes on this form. Guidelines suggested that research assistants request an additional folder with an AORR and review it instead, but they had problems with this method. "One had to search through files to trace these notes, and they were mostly found in doctors' progress notes

⁴² RA Reports 1, Newcastle Hospital, <http://www.healthnet.org.za/mrcgroup/saaip/msg00004.html>. [Restricted access]

⁴³ RA Reports 1, Edendale Hospital, <http://www.healthnet.org.za/mrcgroup/saaip/msg00001.html>. [Restricted access]

which—in most cases—were loose pages. No single file had the notes securely attached to each other to prevent pages from getting lost,” they reported.⁴⁴

At one hospital, only 44 of the required 50 files were collected for the first data collection and only 39 files for the second.⁴⁵ In several hospitals, research assistants reported that “no major surgery was done,” that cases were referred elsewhere, and that elective surgery was the exception rather than the rule since emergency cases were more often performed in these rural hospitals before referral to larger, urban ones.

Other factors may have influenced the data collection process. In one hospital no major cases could be performed due to a lack of equipment, although a senior surgeon had been employed by the hospital for three months.

In the data retrieval process, research assistants attempted to trace the surgical record in the patients’ record provided by the medical records department. If the record was not there, research assistants assumed that the surgeons had not completed one. No attempt was made to determine whether the patient had a duplicate file or to interview the doctor to find out if a record had been completed.

Indicator 7: Completeness and Accuracy of Ward Stock Medicine Labeling

This indicator is important because it is not influenced by any of the

confounders, such as communication difficulties, staff support, etc., that influenced the results of the other indicators. It is thus the only indicator used by the researchers that objectively measures the impact of the accreditation program.

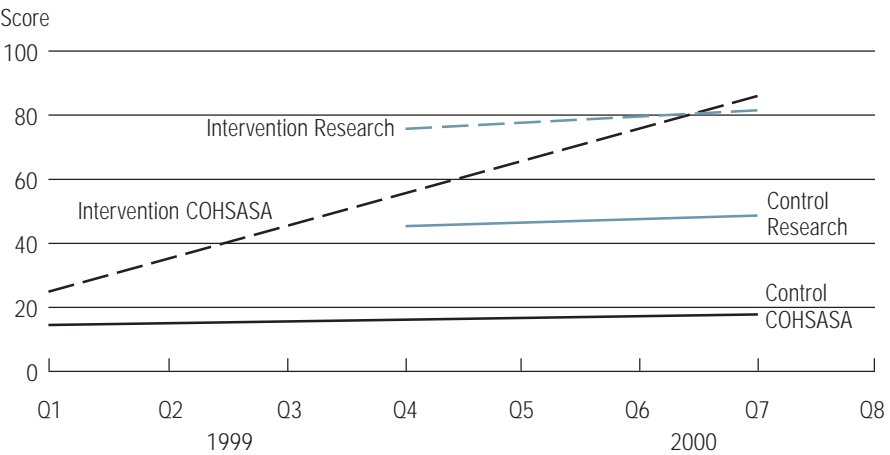
The research assistants examined 50 ward stock containers in the medical, surgical, and pediatric wards. A four-item review of pharmacy stock labeling (correct contents, strength, batch number, expiration date) was undertaken in the wards to indicate whether medication management on wards was both safe and effective. The research assistants found that ward stock labeling improved in both intervention hospitals (from 66 to 82 percent) and control hospitals (from 46 to 50 percent) over the study period. The control hospitals were significantly weaker than intervention

hospitals at both time periods. Figure 9 illustrates this graphically.

Figure 9 shows that in the control hospitals the research indicator and COHSASA proximate cluster scores did not change significantly through the study period. But the figure shows significant positive changes in the intervention hospitals for both the research indicator and the COHSASA proximate cluster scores. This positive trend is evident in spite of the nine-month difference between the baseline standard compliance measurements and first indicator data collections.

At the time of the first research indicator data collection, the intervention hospitals had been in the COHSASA program for approximately 12 months. This would explain why the control hospitals were significantly weaker than the intervention hospitals at that point.

Figure 9
Gain in Ward Stock Labeling, Control and Intervention Hospitals
Research Indicators vs. COHSASA Proximate Clusters



⁴⁴ RA Reports 5, Murchison Hospital, <http://www.healthnet.org.za/mrcgroup/saaip/msg00005.html>. [Restricted access]

⁴⁵ RA Reports 2, Murchison Hospital, <http://www.healthnet.org.za/mrcgroup/saaip/msg00017.html>. [Restricted access]

Similarly, at the second data collection the intervention hospitals had achieved 82 percent, significantly better than the 50 percent in the control hospitals.

The impact of the accreditation program also explains the differences between the intervention and control hospitals with regard to the batch number labeling and expiry date labeling. The researchers report that “the main weaknesses in labeling related to batch numbers and expiration dates.”⁴⁶ Among intervention hospitals, labels with batch numbers rose from 68 to 82 percent and those with expiration dates rose from 84 to 90 percent. Both of these stayed fairly constant in control hospitals: Labels with batch numbers rose from 46 to 50 percent and those with expiration dates fell from 66 to 64 percent. For both types of hospitals, all other labeling in Time 2 exceeded 90 percent.

The percentage of expired drugs on wards was nearly the same in Time 1 for intervention hospitals (6 percent) and control hospitals (5 percent). This rose to 12 percent for intervention hospitals in Time 2 due to one outlier hospital that had an extremely high expiration rate of 58 percent. For control hospitals in Time 2, expired drugs were nearly the same (4 percent) as their Time 1 score. This can be explained by the fact that only one hospital had achieved a level of standard compliance for which it could receive accreditation status. Other hospitals required more time and thus had not made the same progress. This explains the outlier and why the mean indicator

effect of nearly 12 percentage points was not significant ($p < 0.112$).

This is the only indicator that was not influenced by confounders and problems of data collection associated with the majority of the other indicators.

Indicator 8: Hospital Sanitation

This indicator, like the accuracy of ward stock medicine labeling indicator, does not rely on staff support, patient compliance, or good communication with the hospital. It can be seen that both the intervention and control hospitals improved slightly over the study period, but the changes were not significant. However, socioeconomic factors are likely to have been a significant confounding factor.

In the poor socioeconomic circumstances that patients find themselves, soap and towels are sought-after commodities. The temptation to remove these items is great and theft is a common problem. The absence of soap and toilet paper is less a reflection of poor hospital sanitation than a symptom of endemic pilferage. Although there are no statistics to calculate how much soap and toilet paper is lost each year to such theft, the fact that it occurs is beyond dispute.⁴⁷ All public hospitals, particularly rural hospitals, have a great deal of difficulty with theft. In many rural areas patients come from very deprived backgrounds and soap or towels are likely to be removed as fast as they are supplied. The

solution to this problem lies in improving the socioeconomic situation of the community, and the FAP program is unlikely to be able to bring about the improvements within the society that could influence this indicator.

Research assistants felt that the subjective scoring aspect of this research indicator introduced an inaccurate bias because many of the patients in these hospitals do not have toilets, bathrooms, or running water at home. In view of the strong socioeconomic factors that influence this indicator, it is not a good indicator for measuring the impact of an accreditation program.

Leaking taps and inoperative toilets in the intervention hospitals were identified and repaired in the course of addressing non- and partially compliant criteria in the maintenance and housekeeping service elements of the COHSASA accreditation programs.⁴⁸

Discussion of Eight Research Indicators and the COHSASA Proximate Clusters

Since only one hospital achieved accreditation and approximately half of the remaining hospitals were far from the required level for accreditation (at the time of the external survey and second indicator data collection stage), a significant positive change in research indicator scores would only be expected in those indicators where the COHSASA proximate clusters showed substantial compliance.

⁴⁶ This indicator assessed only the presence or absence of batch numbers and expiration dates. It did not determine their accuracy.

⁴⁷ Interview with senior KwaZulu-Natal Department of Health official (A), March 4, 2003.

⁴⁸ Interview with senior KwaZulu-Natal Department of Health official (B), March 4, 2003.

Experience has shown that, in general, substantial compliance with COHSASA standards is reached with scores exceeding 80. If a score of 80 is used as a marker of standard compliance, only three indicators had exceeded this level, namely, "nurse perceptions of quality," "ward stock labeling," and "completeness of peri-operative notes."

The ward stock-labeling indicator. This was the only indicator that was not influenced by difficulties associated with data collection. It showed a significant difference between the control and intervention hospitals at both indicator data collection points.

The nursing perception of quality indicator. In the research indicator results, the difference between control and intervention hospitals was statistically significant. The COHSASA proximate cluster shows an increase from 57 to 83, which correlates with the upward trend of the intervention research indicator.

The completeness of peri-operative notes indicator. Operating theaters are a high-risk area, so one could expect good record keeping because of the potentially severe medico-legal consequences that could arise. The baseline research indicator and COHSASA proximate cluster were relatively high, scoring around 70. The second data collections showed that in the intervention hospitals both the research indicator and the COHSASA proximate cluster increased. However, the increase in the COHSASA proximate cluster was more pronounced. Conversely, in the control hospitals the external survey showed a decrease in the COHSASA proximate cluster. Further analysis of data revealed that the

Table 3
Summary of Research Indicator and COHSASA Proximate Cluster Scores in Intervention Hospitals for All Eight Research Indicators

Research Indicator	COHSASA Proximate Cluster Scores at Baseline and External Surveys	Research Indicator Scores in Intervention Hospitals at 1 st and 2 nd Indicator Collections
1. Nursing perceptions of clinical quality	57.0–83.5	59.3 – 60.8
2. Patient satisfaction	41.1–75.4	86.9–91.5
3. Medication education	49.6–70.8	42.9–43.1
4. Record retrieval	48.7–63.2	85.4–77.5
5. Record completeness	67.3–73.1	47.1–49.1
6. Peri-operative notes	75.3–97.9	70.2–72.7
7. Ward stock medicine labelling	25.6–86.0	66.0–81.8
8. Hospital sanitation	50.8–75.8	59.7–62.8

decrease was due to a reduced number of records with evidence that informed consent was obtained from patients as well as a general decline in record keeping. A similar decline was not noted in the research indicators, which showed a slight increase.

The reasons for the differences detected may lie in the fact that many of the study hospitals do not carry out general surgery, but refer patients onward. Others do. The complexity of surgery performed also varied from hospital to hospital. Given the operational differences, it is difficult to develop discriminating indicators. This difference was compounded by time constraints that resulted in the indicators having to be adapted halfway through the study and reduced and simplified. This, in conjunction with the difficulties experienced in collecting the data, may explain the confused results.

In general, the results produced by all the other indicators were predictable, given the COHSASA proximate cluster scores and the problems associated with data collection as described in this report. All the other COHSASA proximate clusters scored less than 80 and consequently significant improvements would not be expected. The low scores of the majority of the research indicators confirm this conclusion. These results are explained by the fact that the majority of hospitals had not reached accreditation status.

In spite of the many difficulties experienced in data collection, the vigor of the format for a randomized control trial revealed trends between the intervention and control hospitals.

In the majority of indicators chosen, in general, it was found that the research indicators produced similar results to those of the COHSASA

proximate clusters. The fact that only one hospital had been accredited made it unlikely that significant changes in the research indicators would be detected. However, positive trends would be expected and were found in the majority of indicators.

In those COHSASA proximate clusters in which significant compliance was achieved (with the exception of the “completeness of peri-operative notes” indicator), a significant difference between the intervention and control hospitals was found. These results suggest that the COHSASA scores reflected the changing situations as hospitals moved through the COHSASA program. Despite the limitations of time and management support, and resource constraints that impacted negatively on the capacity of the hospitals to reach accreditation, there were significant improvements in all sections of the intervention hospitals compared to the control hospitals.

There were two general factors that compromised the ability of the research indicators to measure the impact of the accreditation program, one relating to the indicators and one to time frame, as summarized below.

The reduced number of simplified research indicators. The narrow focus and small number of research indicators used in this research limited its capacity to meaningfully evaluate the impact of the COHSASA accreditation program.

The limited time to plan, develop, and validate indicators and data-gathering methods, including:

1. The limited time to implement the indicator research component in

- order to correspond with the standard compliance component;
2. The lack of support of the research assistants in the field, particularly during the first data collection phase;
3. The poor communication with the hospitals;
4. The lack of support shown by the hospitals to the research assistants;
5. Data-gathering methodologies that did not take into account the difficulties that the research assistants would experience in the field;
6. Poor timing of the second data collection; and
7. The failure to repeat data collections when external surveys were postponed.

There were also a number of indicator-specific factors that were essential in order to achieve valid and reliable results, as summarized in Table 4.

VI. Lessons and Conclusions

Where hospitals are located in areas of poor socioeconomic conditions and where they have been poorly resourced over a number of years, the following should be taken into account if outcomes research is to be carried out:

1. Adequate time should be allowed for planning.
2. Indicators should be carefully developed, using evidence-based methods where possible and validated before being used in the research program.
3. There should be thorough field checking to ensure the validity of data collection methods prior to the research.
4. Good external and internal communication channels should be established with and within the hospitals before the research commences.

Table 4
Factors That Influenced the Reliability of the Indicator Data

Indicator Number	1	2	3	4	5	6	7	8
Congruence between research indicators and COHSASA proximate clusters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Compatible scores between research indicators and COHSASA proximate clusters	No	No	No	Yes	Yes	No	Yes	Yes
Patients were cooperative	NA	No	NA	NA	NA	NA	NA	NA
Hospital staff were cooperative	No	No	NA	No	No	NA	NA	NA
Good data retrieval methods	No	No	No	No	No	No	Yes	No
Data retrieval satisfactory	No	No	No	No	No	No	Yes	No
Good socioeconomic factors	NA	No	No	No	NA	NA	NA	No

NA = not applicable

5. Ensure that hospitals understand the nature of the research and their commitment is obtained.
6. Research assistants should be supported in the field.⁴⁹ Researchers should visit the hospitals with the research assistants, particularly in the early stages.
7. Communications lines between the field staff and the researchers should be established and kept open at all times.
8. Data collections should be timed so that they are carried out at the appropriate time to ensure that they do not clash with other research activities.
9. Data collection in hospitals should be repeated if activities associated with the research questions are delayed and the hospital data were collected in advance of the research activities.

This study demonstrated that when measuring the impact and implementation of accreditation programs in compromised hospitals, careful and timely planning of research is critical.

It also showed the difficulty in developing and using indicators that provide reliable results. The importance of the validation of indicators and of the data-gathering methods prior to the research was clearly demonstrated.

Communication was found to be an essential ingredient of the research effort, as was the need to obtain the support and co-operation of hospital staff.

Failure to consider these important elements cast doubt on the validity of all but one of the indicators used.

The accreditation standard compliance component showed that the FAP produced significant improvements in standard compliance in all services of the intervention hospitals.

The study demonstrated the difficulties experienced by compromised hospitals in complying with the standards. The importance of management commitment to the process was of particular significance.

Future research should be based on sufficient indicators to comprehensively evaluate all hospital services and should not be limited to those areas that provide accessible, convenient data.

VII. Recent Developments at COHSASA

Because it is COHSASA's policy to continuously evaluate the effectiveness of its quality improvement initiatives, it has developed a range of new systems and processes over time to meet some of the challenges that have been identified in this and other research studies, feedback from the field, and internal quality improvement programs.

The value of hospital and management commitment in ensuring the effectiveness of the COHSASA program was highlighted in this study. This has led to various developments, for example, the incorporation of performance agreements between provincial authorities and the chief executive

officers of hospitals to expedite the quality improvement process. Moreover, efforts are also made to ensure that hospital management demonstrates the necessary commitment before the program is actually implemented.

In order to provide hospital management with ongoing, continuous, and updated information about the status of quality improvements in their facilities, a system of regular evaluative report-backs has been introduced. These reports provide a master plan to enable management to identify deficiencies and thereby plan and prioritize improvements.

One of the problems that has been identified, not only by this study but also through COHSASA's ongoing observation and monitoring, is that disadvantaged hospitals need more time to institutionalize quality improvement efforts to achieve sufficient compliance with standards to reach accreditation status.

COHSASA has therefore introduced a program of "Graded Recognition," whereby hospitals are acknowledged for gradual but specific improvements in their service delivery. Selected indicators of quality delivery—in the fields of management and leadership, service delivery, and the capacity to evaluate—have been grouped together in such a way as to yield progressive but contiguous levels of achievement. These various stages of improvement are recognized by certification and act as motivating factors to help the hospitals, particularly those operating from poor resource bases, to move forward in the facilitated process.

COHSASA has been accredited by the International Society for Quality

⁴⁹ This support was evident in the latter part of the study.

in Health Care (ISQua) following an independent survey against the ALPHA International Standards for national healthcare accreditation

bodies. This accreditation is valid until 2006. In addition, ISQua has awarded COHSASA a certificate of recognition following an indepen-

dent assessment against the ALPHA International Principles for Health Care Standards.

Appendix: Measurable Elements in COHSASA Proximate Clusters Corresponding to the Eight Research Indicators ^(a)

1: Nurse Perceptions of Clinical Quality, Participation, and Teamwork

1. Professional staff discuss and find agreement on common policies and procedures for medical inpatient services at meetings, which are held with hospital management at least every three months. (8.2.2.4) ^(b)
2. Doctors participate in multi-professional team discussions (e.g., ward rounds) to ensure coordinated care of the patient. (8.2.2.7)
Conclusions of discussion and consultation between doctors and other health professionals are recorded on the patients' health records. (8.2.2.8)
3. The requirements of the medical in-patient service for staff are based on a system of measuring work load and skills mix. (8.2.3.1)
4. Nursing staff allocation ensures that appropriate nursing expertise and experience is available to ensure continuity of care for 24 hours. (8.2.3.2)
5. Staff in the medical ward/department are supported by appropriate administrative, auxiliary and secretarial personnel. (8.2.3.5)
6. There is a system to facilitate individual and collective ethical decision-making in the service. (8.3.1.4) ^(c)
7. A support system is available to service staff confronted with significant ethical problems (e.g., multi-professional discussions, debriefing sessions, counselling service.) (8.3.1.5)
8. The principles of fair labour practice as described in the hospital's industrial relations policy are applied in the service. (8.3.1.6)
9. Staff of the medical in-patient service, including surgical, paediatric and obstetric services, are actively involved in the formulation of policies, procedures and protocols for the service. (8.4.1.3) ^(c)
10. Evidence-based scientific nursing care is practised. (8.6.2.1)
11. The execution of nursing care is delegated in accordance with the Scope of Practice Regulations of the professional body of each nurse category. (8.6.2.3)
12. An individualized, written nursing care plan for each patient is available based on the assessment of the patient. (8.6.2.4)

2: Patient Satisfaction

COHSASA standard 1.7.1 on the rights of patients requires hospitals to ensure that:

1. The patient has the right to considerate and respectful treatment. (1.7.1.8)
2. The patient has the right to privacy. (1.7.1.11)
3. The patient has the right to participation in her/his medical treatment. (1.7.1.16)
4. The patient has the right to knowledge of the identity of the physician primarily responsible for her/his medical care and the way to contact the physician. (1.7.1.17)
5. The patient has the right to complete information from a physician concerning her/his health status, unless medically contra-indicated. (1.7.1.19)
6. The patient has the right to information about the nature and purpose of any clinical procedures that will be performed, as well as who will perform the procedures. (1.7.1.20)
7. Policies and procedures are developed for patients' privacy including confidential conversations with the reception personnel. (2.6.6.12)
8. An individualised written nursing care plan for each patient is available based on the assessment of the patient. (8.6.2.4)
9. The continuous evaluation of the patient is recorded with full account given to the nurses responsible for the nursing care. (8.6.2.4)
10. The date and time of admission to the ward/department is recorded, and the time the doctor was notified of the patient's admission. (8.7.2.1)
11. The patient record includes notes on continuing assessment and evaluation of needs. (8.7.3.10)
12. The management team appoints a Health Care Technology Advisory Committee (HTAC) to advise on planning for equipment acquisition, deployment, utilisation and maintenance. (1.6.3.1)
13. Where there is no regional clinical engineer, a person is appointed by the hospital management to be responsible and accountable for the day-to-day coordination of clinical engineering services and technical aspects relating to the safety of medical

equipment, including liaison with outside providers. (1.6.3.4)

14. There is a mechanism to ensure that hospital and service policies and procedures are known to and implemented by personnel working in the housekeeping service. (14.4.1.8)

3: Medication Education

1. Nursing management ensures that medicine is administered to patients in accordance with legal requirements through participation in nursing documentation and meetings. (3.6.1.4)
2. There are policies and procedures for patient information on medicine. (8.4.3.7)
3. There is a policy and procedure for education and counselling services offered to patients and their families. (9.4.5.2)
4. There is a policy and procedure for information leaflets issued to the patients or carers. (9.4.5.3)
5. There are facilities for confidential consultations. (9.5.2.9)
6. There is a designated waiting area with adequate seating for the maximum expected number of patients. (9.5.4.1)
7. Information on waiting time is available. (9.5.4.6)
8. The hospital's patients' rights document is displayed in the pharmaceutical service. (9.6.1.3)
9. An implementation report on patients' rights is provided to management every six months. (9.6.1.4)
10. Patients receive consistent, reliable counselling on medication to improve compliance and ensure safe use of medicines. (9.6.1.6)
11. The patient is given clear oral instructions on the purpose and use of their medication, including at least how much, how often, and for how long their medication must be taken and what common side effects may be expected. (9.6.1.7)
12. Patients are given both written and oral instructions. (9.6.1.8)
13. There is a system to ensure that patients and their carers understand instructions for taking of medication. (9.6.1.9)
14. The hospital's system for providing translation services is known to and applied by staff in the pharmaceutical service. (9.6.1.11)
15. All dispensed medicine is clearly labelled with the patient's name, the drug name, the strength of the drug, quantity and dosing instructions. (9.6.1.12)

16. Details of medical treatment prescribed are recorded in the notes, as well as on the prescription sheets. (39.1.6.8)

17. There is evidence that the patient and carer are fully informed of medical findings and participate in decision making relating to treatment. (39.1.6.9)

4: Medical Record Accessibility and Retrieval Accuracy

1. There is a documented system that allows for rapid retrieval and distribution of health records. (2.6.7.6)
2. There is an effective monitoring system (e.g., tracer cards) whereby records can be traced within the facility at all times. (2.6.7.7)
3. The filing system allows for incorrectly filed records to be easily identified (e.g., colour coding). (2.6.7.8)

5: Medical Record Completeness

1. The medical record notes provide a relevant, chronological account of the patient's care and support for clinical decisions. (8.7.1.1)
2. The date and time of admission to the ward/department is recorded, and the time the doctor was notified of the patient's admission. (8.7.2.1)
3. The patient's record contains a written, provisional admission diagnosis. (8.7.2.2)
4. The notes include the reasons for admission. (8.7.2.3)
5. The notes include the results of the physical examination. (8.7.2.6)
6. The notes include details of relevant health history. (8.7.2.7)
7. The notes include a summary sheet/problem list, which contains significant diagnoses and procedures. (8.7.3.2)
8. The notes include a statement of the patient's needs and expected outcomes. (8.7.3.3)
9. The notes include name, signature and designation of the professional staff member responsible. (8.7.3.4)
10. The notes include progress notes/clinical consultations. (8.7.3.5)
11. The notes include orders for special diagnostic tests and their results. (8.7.3.6)
12. Medication prescriptions are written, dated and signed by qualified medical practitioners. (8.7.4.1)
13. The notes include a record of all medication administered. (8.7.4.4)
14. The discharge summary includes the final diagnosis with diagnostic code. (8.7.5.1)

15. The discharge summary includes instructions given to the patient concerning follow-up care. (8.7.5.3)
16. A copy of the discharge summary is handed to the patient/carer on discharge. (8.7.5.4)
17. The notes provide a relevant, chronological account of the patient's care and support for clinical decisions. (10.7.1.1)
18. The date and time of admission to the ward/department is recorded, and the time the doctor was notified of the patient's admission. (10.7.2.1)
19. The patient's record contains a written provisional admission diagnosis. (10.7.2.2)
20. The notes include reasons for admission. (10.7.2.3)
21. The notes include the results of the physical examination. (10.7.2.6)
22. The notes include details of relevant health history. (10.7.2.7)
23. The notes include a summary sheet/problem list, which contains significant diagnoses and procedures. (10.7.3.2)
24. The notes include a statement of the patient's needs and expected outcomes. (10.7.3.3)
25. The notes include name, signature and designation of the professional staff member responsible. (10.7.3.4)
26. The notes include progress notes/clinical consultations. (10.7.3.5)
27. The notes include orders for special diagnostic tests and their results where applicable. (10.7.3.6)

6: Completeness of Peri-Operative Notes

1. The pre-anaesthetic assessment of each patient is performed by the anaesthetist who is administering the anaesthetic. Where this is not possible, it is done by another anaesthetist who documents the findings and communicates them to the administering anaesthetist. (1.6.1.2)
2. There is evidence of informed consent to the procedure. (1.6.1.3)
3. The anaesthetist is responsible for supervising the recovery period and authorising the patient's discharge. (6.6.1.9)
4. There is an operating theatre record in each patient's file. (6.6.2.1)
5. Each record shows the date of the procedure, and the times that anaesthesia and surgery were commenced and completed. (6.6.2.2)
6. Each record contains the names of the surgeons, surgical assistants, anaesthetists, anaesthetic assis-

tants and nurses attendant at the procedure and during the post-anaesthetic recovery stage. (6.6.2.3)

7. The pre-operative diagnosis and investigations are recorded. (6.6.2.4)
8. Each surgical record contains details of the surgical procedure performed. (6.6.2.5)
9. Each surgical record contains details of tissue removed, altered or added. (6.6.2.6)
10. Each surgical record contains details of specimens sent for histology. (6.6.2.7)
11. Each surgical record contains signed post-operative orders. (6.6.2.8)
12. Each surgical record contains details of dressings and drainage systems. (6.6.2.9)
13. Each surgical record contains details of prostheses inserted if applicable. (6.6.2.10)
14. An anaesthesia record is kept. (6.6.3.1)
15. Each anaesthesia record contains details of the medical history taken by the anaesthetist prior to the anaesthesia. (6.6.3.2)
16. Each anaesthesia record contains details of the physical examination conducted by the anaesthetist prior to the anaesthesia. (6.6.3.3)
17. Each anaesthesia record contains details of any specific pre-anaesthetic investigations. (6.6.3.4)
18. Each anaesthesia record contains the anaesthetic technique, patient responses to anaesthesia, and difficulties encountered, if any. (6.6.3.5)
19. Each anaesthesia record contains the details of the routine monitoring of patient parameters, e.g., blood pressure, heart rate and saturation. (6.6.3.6)
20. Each record contains details of intravenous fluid therapy, if used. (6.6.3.7)
21. There is a recovery room record in the file. (6.6.3.8)
22. Each recovery room record contains details of the recovery observations, including state of consciousness, colour, respiration, pulse and blood pressure, state of pain relief, and drainage and oozing. (6.6.3.9)
23. Each recovery room record shows the times when the patient entered, and was discharged from, the recovery room. (6.6.3.10)

7: Completeness and Accuracy of Ward Stock Medicine Labelling

The management of the medical in-patient service ensures that the following policies and procedures are in place:

1. There are policies and procedures for stock control, ordering and storage of medicines. (8.4.3.1)

2. Policies and procedures relating to the safe-keeping, checking and recording of scheduled drugs comply with current legislation. (8.4.3.3)
3. There are policies and procedures for patient information on medicine. (8.4.3.7)
4. There are policies and procedures on the labelling of medication. (8.4.3.8)
5. There are policies and procedures for the checking of expiry dates, and dealing with expired medicines. (8.4.3.9)
6. There is a policy and procedure in the pharmaceutical service for the storage and handling of medications within the hospital, including ward and theatre stock with regard to statutory regulations. (9.4.3.6)

The management of the paediatric service ensures that the following policies and procedures are in place:

7. There are policies and procedures for ordering, stock control and storage of medicine. (10.4.3.1)
8. Policies and procedures relating to the safekeeping, checking and recording of scheduled drugs comply with current legislation. (10.4.3.2)
9. There are policies and procedures for patient information on medicine. (10.4.3.7)
10. There are policies and procedures on the labelling of medication. (10.4.3.8)
11. There are policies and procedures for the checking of expiry dates, and dealing with expired medicines. (10.4.3.9)

The management of the obstetric/maternity and surgical in-patient services ensures that the following policies and procedures are in place:

12. There are policies and procedures for ordering, stock control and storage of medicine. (11.4.4.1)

8: Completeness of Hospital Sanitation

In medical, surgical and obstetric/maternity in-patient services, patient accommodation is adequate to ensure effective care and the safety and

1. There is at least one bath or shower per 12 patients. (8.5.3.3)
2. There is at least one toilet for each 8 patients or part thereof (in male wards a urinal may be substituted for every third toilet). (8.5.3.4)
3. The numbers and types of toilets and baths are adequate to meet the number of children accommodated, based on their needs and age groups. (10.5.5.1)

The management of the housekeeping service ensures that dated, written and signed policies and procedures are developed and maintained.

4. Policies and procedures are available relating to appropriate cleaning methods and materials for various surfaces. (14.4.2.5)

Notes: (a) The numerals at the end of the COHSASA measurable elements refer to the numbered paragraphs in the COHSASA manual describing the measured elements. (b) All the criteria selected for this COHSASA-measured element apply to medical, surgical, paediatric, and maternity/ obstetric departments. (c) This particular criterion applies to the medical inpatient department, but similar measurable elements apply to the surgical, paediatric, and maternity/ obstetric departments.

Commentary by Anne L. Rooney⁵⁰

The challenge of identifying a clear relationship between healthcare structure, process, and outcome measures has stymied researchers and healthcare accreditation professionals for decades, although on first glance the connections between the three may seem simple and straightforward. Intuitively one might reasonably surmise that improved or standardized structures or processes within a hospital should result in an enhanced likelihood of achieving positive patient outcomes while at the same time avoiding negative ones. In addition, an organized and systematic process of ongoing quality monitoring, such as that imbedded in most accreditation programs, implies a continuous feedback loop in which a hospital assesses its own outcomes and makes organizational improvements when needed.

An example of this can be illustrated in the area of hospital infection control. One might expect that compliance with accreditation program structure standards (e.g., infection control policies, the availability of personal protective equipment such as gloves) as well as process standards (e.g., healthcare practitioners using sterile technique in performing surgical procedures) should help to reduce the risk and rate of nosocomial infections. Although seemingly a reasonable conclusion, evidence demonstrating this relationship has been difficult to capture.

That is why, despite its well-articulated limitations, this COHSASA accreditation impact research study makes such an important contribution to this nascent body of knowledge. The lessons we have gleaned from it—the challenges of identifying sensitive metrics and data sources, data collection difficulties in a developing country context, and the actual time it takes for institutional changes to positively affect patient care processes and outcomes—will certainly serve to inform any future research studies of this type. In the end, healthcare accreditation programs in both developed and developing countries are intended to serve as a stimulus for improvement in healthcare quality and safety; thus increasing our knowledge about the complex interplay of factors involved in achieving these improvements will help both accrediting bodies and accredited organizations to optimize the potential societal gains associated with this method of standards and external quality evaluation.

While a number of health services research studies (Nolan et al. 2001; Jessee and Schranz 1990; Luft and Romano 1991) have examined the impact of hospital managerial or operational characteristics (e.g., a management philosophy of continuous quality improvement) on measures such as patient satisfaction or clinical outcomes, to date there are very few studies that critically address the impact of accreditation as a quality management and external evaluation tool in

improving either organizational or clinical outcomes. The possible reasons for this dearth of credible evidence are multiple:

1. Research design challenges, such as identifying a comparison or control group to study, particularly in countries where accreditation is long-standing and widespread.
2. Accreditation standards are traditionally developed through a professional consensus of experts rather than through a reliance on evidence-based research studies (Scrivens 1997).
3. Difficulties in selecting outcome indicators or metrics that are directly linked to structures and processes and also largely within the hospital's ability to control.
4. Patient safety and healthcare quality are constantly impacted by multiple environmental factors and inputs, making it difficult to develop metrics sensitive enough to distinguish the impact of accreditation from many other factors in a prospective analysis (Loeb 2001).
5. The methodological challenges associated with using outcomes as a marker of quality, since it requires an adjustment for differences in case mix and other external factors to ensure fair comparisons among institutions and physicians (Brook et al. 2000).

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6. The availability of “capturable” indicator data and the constraints of obtaining patient-level data.
7. The length of time for change and innovation to be institutionalized by hospital leaders and staff and eventually demonstrated through improvements in outcomes.
8. A key impact of accreditation is its ability to provide monitoring and oversight to ensure that improvements are sustained over time; however, at the same time such a potentially long (e.g., 5–10 years) research period is both challenging and costly to implement.

In the United States, this examination of impact has been particularly difficult at the hospital level, since accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accrediting bodies has existed for 50 years or more, and greater than 80 percent of U.S. hospitals are currently accredited. This figure translates to the fact that 95 percent of the operating hospital beds in this country are presently located within accredited hospitals, making a comparison or control group of non-accredited hospitals virtually impossible.

However, one example of a national survey study conducted in the U.S. in the mid-1990s analyzed the determinants of compliance with a new smoke-free environment standard that had recently been published by the JCAHO (Joseph et al. 1995). The researchers found that the majority of study hospitals were in compliance with the standard within the first year of its adoption, and the duration and timing of the hospitals’ smoke-free policies suggested that the JCAHO accredi-

tation standard was influential in accomplishing this goal. The researchers further concluded that in addition to protecting patients from harm and hospital employees from environmental smoke, the smoke-free initiative also stimulated many hospitals to intensify their smoking cessation programs. Although it is nearly impossible to prove a causal relationship between compliance with the smoke-free environment standard and actual smoking cessation rates within the patient population, the accreditation standard clearly laid the foundation for a greater awareness of this health risk, hopefully positively impacting patient behavior down the road.

A 1983 study on the impact of the Australian hospital accreditation program attempted to discern the impact of that program as a catalyst for hospital change in New South Wales (Duckett 1983). While the researcher concluded that hospital accreditation had a differential impact on various components within the hospital, such as in improved communications and management decision making, the measures used to make this determination were largely based on the development of new hospital structures (e.g., a framework of hospital committees, organizational charts, procedures for credentialing practitioners). No patient outcome measures were studied in the Australian research, likely because of the significant methodological challenges of identifying and measuring outcome indicators truly associated with the expected impact of accreditation standards.

A recent U.S. study by researchers at the University of Michigan (Griffith et al. 2002) attempted to make the

linkage between accreditation findings and several general outcome measures and concluded that the accreditation scores were not positively correlated with selected Medicare performance measures. However, a number of these Medicare measures addressed financial performance, such as hospital cash flow and asset turnover, areas not traditionally addressed or thought impacted by accreditation standards. Even though mortality and complications data were also considered, their validity as indicators of quality was strongly challenged as being too global in nature and difficult to adjust for risk. Indeed, even the federal government stopped publishing hospital-specific mortality data almost a decade ago for this very reason. (JCAHO 2002).

In the final analysis, what can we learn from these various studies, including the COHSASA accreditation impact research? Is it possible to measure credible outcomes expected to be impacted by compliance with accreditation standards and the process of external quality evaluation itself? Given the significant resource constraints within most national healthcare systems today, does accreditation truly represent an effective health policy and quality initiative? If one believes that standardizing and improving healthcare structures and processes optimizes the opportunity for positive patient outcomes to result—even if this relationship is difficult to demonstrate in a time-limited prospective study in a statistically significant manner—then the answer is a resounding yes.

A 1999 evaluation of the accreditation in the U.S. by the Office of

Inspector General found that despite its limitations, accreditation as an external quality review mechanism played an important role in protecting patients from harm and in complementing the hospital's own internal quality efforts (Office of Inspector General 1999). Similarly,

the changes in COHSASA standards compliance as seen in the intervention hospitals were dramatic and widespread across many areas of hospital operations, leading one to conclude that accreditation does serve a unique role in stimulating a hospital's quality initiatives. One

could reasonably expect that over time the internalization of these standards into daily work processes will also result in demonstrable differences in other indicators, such as the kind used in this important research study.

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